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# A NEW PERSPECTIVE ON THE PRODUCT PORTFOLIO MANAGEMENT OF PHARMACEUTICAL COMPANIES: A CASE STUDY OF CLOSED JOINT-STOCK COMPANY ZAO «SEVERNAYA ZVEZDA»

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**THESIS**

**ABSTRACT**

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The purpose of this thesis was to review the theoretical foundations of product portfolio management for company competitiveness and implement of certain tools for pharmaceutical manufacture CJSC ZAO «Severnaya Zvezda».

The study was conducted in three stages. The first chapter consider research of popular matrix methods of porfolio managment. Despite the great interest to this theme, consensus on a comprehensive approach to its formation and analysis not reached. However, enterprises use simplified or approximate techniques of product portfolio management. At the same time, ever-changing market requires modifications of existing ways of analysis. The next stage describes the process of developing management model and proposals to clarify the classification of goods in accordance with needs of different consumer groups. The third stage of work involve demonstration of the designed method on the example of the enterprises portfolio, its new view and analysis with suggested algorithm.

It is necessary to develop simplified methods of portfolio analysis, allowing to carry out the partial analysis or to test a certain product within the given time period. The model will allow controlling strategic trends of business development, balancing and managing the product portfolio without excess costs and the consumer will be satisfied with the offered product range.


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# PREFACE

I would like to give my gratitude to my parents for their support. Next I want to thank my supervisor Anas, who believed in me and helped to overcome my inner barriers. Thanks to Kajaani University of Applied Sciences and to the dean of the E&M faculty Korshunova E. D. from Moscow State University of Technology "STANKIN" for the opportunity to study abroad.

CONTENTS

# 1 INTRODUCTION

Market relations in the period of 2014 - 2015 years have been characterized by enhanced instability, the presence of uncertainty of the environment, increased competition between manufacturers. Sanctions against Russia, the import substitution program, the state program for the replacement of imported goods, budget deficit and reduction of purchasing power forcing manufacturers rapidly satisfy demand of different groups of consumers and maintain competitiveness. Under these conditions enterprises need to minimize the production costs and the costs of promotion. Reduced investment rating of Russia brought a decrease in financial and intellectual investment. In this regard, before the enterprises sharply rise competitiveness problems and search for additional sources of maintaining economic stability. One of the most important strategic management tools, which help enterprises adapt to the changing market environment, is optimization of the product portfolio.

Optimally matched portfolio affects on sales, enables to control marginal income and net profit shares in the company's revenue. Product Portfolio Management allows operatively make changes to its structure, to maintain a competitive position in the consumer and commodity markets, to optimize capacity utilization and reducing costs. As a result, it provides economic stability of the enterprise. The product portfolio has to be balanced.

Theoretical aspects of the portfolio formation are developing by economists since the second half of the twentieth century. General principles of its analysis and management laid by scientist all over the world: I. Ansoff, D.V. Arutyunova, K. Bowman, A. Vaismana, L.P. Vladimirova, P. Drucker, G. Inozemtsev, A.P. Gradova, F. Kotler, M. Porter, B.D. Henderson, J. Trout, AA Thompson, K. Stern and others. Literature analysis shows that, despite the great interest in this subject there are no common view on the definition of the portfolio, no comprehensive approach to its formation and analysis. However manufactures use simplified or approximate techniques of product portfolio management. At the same time, ever-changing markets require modifications of existing methods and models.

Today many small and medium companies in Russia make decisions based on intuitive assumptions and experience, without paying due attention to the specialized methods of management. With the expansion of the product portfolio, the question of its effective formation and management becomes very important.

The aim of the thesis is to develop theoretical and methodological principles as well as practical advices on managing the enterprise portfolio, using the matrix method.

The main subject of research is the process of product portfolio management, aimed at increasing competitiveness and economic efficiency of enterprises.

The object of the study and the customer is a pharmaceutical company ZAO «Severnaya Zvezda».

Theoretical and methodological basis of the thesis are the results of research scientists in product portfolio management. The study used scientific methods: comparison, analysis, synthesis, concretization, abstraction and other based on the theory of knowledge and the principles of dialectic methods of systematic methodology, methods of economic analysis, statistics, expert evaluations. In this work were used matrix methods of portfolio analysis.

The regulatory basis are the law of the Russian Federation, decisions and orders of the government line ministries (Ministry of Health, Ministry of Industry and Trade of the Russian Federation), the data of the state register of medicines of the Russian Federation, regulations, state standards, guidelines.

The empirical basis are the internal documentation of the company ZAO «Severnaya Zvezda», proceedings of the international and russian scientific-practical conferences, publications in the press, the study of specialized marketing companies (DSM – groups, Pharmexpert and others), the data of medical reference books and studies of author.

The scientific novelty of the research are follows:

- formulated general and specific principles of decision-making for product portfolio management
- offered an algorithm of matrix methods of portfolio analysis for specific enterprise;
- developed a technique of organizing the process of product portfolio management for pharmaceutical industry.

The practical significance of the work lies in the fact that the theoretical results are brought to the level of specific practical recommendations, and may be used for further research, theoretical studies and practical activities of enterprises. In the work was identified the

potential development of the product portfolio of the pharmaceutical manufacture. The portfolio has been divided into groups. Were used additional features of the product to maintain its competitiveness and reduce the costs of promotion.

The recommendations of product portfolio management accounted and used on an enterprise ZAO "Severnaya Zvezda".

The new algorithm of portfolio analysis for pharmaceutical companies will be based on integration of matrix method with international classifications of disease and anatomical therapeutic chemical classification system. Also was proposed a classification of products, according to which the portfolio consists of three product levels. The portfolio consisting of first level products is the simplest for analysis. The portfolio, consisting of third level products, is the most sophisticated for analysis and requires the application of several analysis matrices in order to take the objective strategy. For the purpose of most effective distribution of investment resources between products of different levels it is necessary to additionally evaluate the feasibility, potential risks and strategic development prospects for each of it.

# 2 PORTFOLIO ANALYSIS AND ITS ROLE IN THE STRATEGIC MANAGEMENT

Nowadays enterprises are worried by the decreasing share of the marginal income, as well as of the net profit share in proceeds. This situation is stipulated by different factors, but there are common reasons, namely, "bad" product portfolio (Kulinich, 2013).

In modern competition conditions the market is determined by the product range and the enterprise's task is to satisfy the demand, providing more quality and efficiency products and services than competitors. The level of real and potential profit, the stability of competitive positions at prospective markets, the economic stability and the possibility for a company development depends on the structure of the product portfolio. This requires carry out the planning, creation and management of product portfolio. The enterprise should timely provide a set of goods that fit the profile of its production operations and satisfying customers as much as possible.

The competitive strategy is built on the product portfolio management. The product portfolio is a list of kinds of products, manufactured by the enterprise. All products undergo a certain life cycle in their development, lose its actuality, and become obsolete. The portfolio optimization should be carried out regularly, basing on most modern methods of evaluation and prospective of market products. The company portfolio should be balanced, i.e. shall provide the right combination of subdivisions or products, needing capital for its growth, with economical entities, disposing of some capital surplus. The portfolio analysis can keep balancing such key business factors as risk, money inflow, renovation and regression (Volkova, 2013).

Basic principles of formation optimal portfolio (Arutyunova, 2010):

- diversification of risk;
- diversification of the stages of the life cycle of objects;
- diversification of investment objects and «donors».

## 2.1 The definition of portfolio analysis

The portfolio analysis is a key strategic business component (SBC). This is a method, by means of which strategic business units (SBU) of a company are analyzed cumulatively, allowing revealing key fields of activities, determining the company mission (Vixancky, 1998).

The portfolio analysis gives a clear impression on the field of company's activities, as well as on the mutual relation of business parts, representing it as integral whole. It helps to evaluate economical activities, where funds are invested, and investments to inefficient projects are curtailed or terminated. The portfolio analysis makes it possible to evaluate the relative attractiveness of markets, as well as the competitive ability of each of them. It allows obtaining typical strategic recommendations and is an important stage of marketing strategy development (Tekutjev, 2012) (Kochugueva 2012).

The essence of the portfolio analysis - the company is considered as integrity of strategic business units. The purpose of the portfolio analysis is to coordinate strategies and to use existing investment resources from the point of view of achievement of stable company position in whole, as well as the growth of financial results (Ries, 2014).

In order to distribute investment resources between strategic business units in a most effective way it is necessary to evaluate potential feasibility, risks and strategic prospects for the elaboration each of them. Generally, the portfolio analysis is built on the rule that the higher the potential of a business unit development (sales and profit growth) and the lower risks, the more profitable investment to such unit. Investment resources can be both external and internal (profit of other business units). Also it should be highlighted that analysis allows avoiding the "unifying" approach to the development of such business units while creating corporate strategies. The independent priorities and goals are specified for each business unit, meeting its position in the market, as well as the role in the portfolio (L.K Serga, 2012).

## 2.2 Six Steps of portfolio analysis

According to Vixancky, one of the founders and leaders of the Russian School of Management, portfolio analysis is carried out in six steps. (1998)

The first step is a choice of levels in the organization to analyze the portfolio. It is a prerequisite, since the firm cannot executes the analysis of only on the company's micro level.

The second step - fixing units for analysis, called strategic business units (SEB), to use them for positioning on the matrices of product portfolio. SEB often differ from the production units. They may cover one or more goods that meet similar needs. Some companies are considering SEB as product-market segments.

The third step - definition of the matrix analysis parameters in order to have clarity regarding the collection of necessary information, as well as to select the variables, which will be analyzed. For example, in the study of the sector attractiveness as these variables can serve the market size, the extent of protection against inflation, profitability, market growth rate, the extent of the prevalence in the world market.

The fourth step - data collection and analysis is conducted on many ways, but priority is given four most important areas:

- attractiveness of the industry from the perspective of having positive and negative aspects in the sector, the nature and extent of the risk, etc;
- competitive position of firms in the industry, as well as the overall competitive position of the company;
- opportunities and threats of the enterprise;
- resources and skills, considered from the point of presence at the company's capacity to compete in each of the industries.

The fifth step - the construction and analysis of the product portfolio matrix, which should give an idea of its current state, on the basis of which it is possible to predict the future state of the matrix, and consequently the expected company's product portfolio.

The sixth step - determining the desired product portfolio is carried according parameters which can best contribute to achieving company’s goals.

## 2.3 Matrix methods for analysis of the product portfolio

The most common methods of portfolio analysis are matrices. Such analysis is not decision-making tool. Matrix shows the status of product portfolio, which should be taken into account by management in decision-making. They are usually two-dimensional table, where the values of the axes laid considered factors (an important condition: among factors should not be a strict functional dependence). Quadrants formed by the intersection of border values of both factors. The given quadrant indicates the applicability to business units of standard strategic recommendations.

The following are the most well-known methods of matrix analysis that were used to develop a model management of product portfolio for the ZAO Severnaya Zvezda. The choice of these matrices is explained with the fact that the client is not advanced user of such tools. Analysis of the portfolio must be full, but simple enough to implement, so the company will able to use it on their own, without continuous outsourcing or hiring an additional manager.

### 2.3.1 BCG Growth-Share Matrix

In 1960$^{th}$ Boston Consulting Group has developed BCG Matrix, which is an internal assessment of the products or services offered by the firm (Orcullo, 2007). It provides a basis for evaluation of the relative performance of the businesses in which an organization is operating and making the organization more competitive it also prescribes the preferred distribution of cash and other resources among these businesses (Griffin, 2008).

The matrix consists of two axes: one showing market growth and the other showing market share. The resulting four quadrants form the categories by which an organization can classify its business units or products on the basis of their relative market shares and growth rates (Boston Matrix). Matrix classifies the types of business units into four categories as stars, question marks, cash cows and dogs (See Figure 1). Company must have range of products both with high growth potential (requiring investments of cash) and goods with low growth potential (delivering cash) to ensure long-term value creation. According to the matrix, in the product portfolio should be several cash cows, 1-2 stars, a few question marks, and the

minimum number of dogs. The advantages and disadvantages of using this method are shown in Table 1.

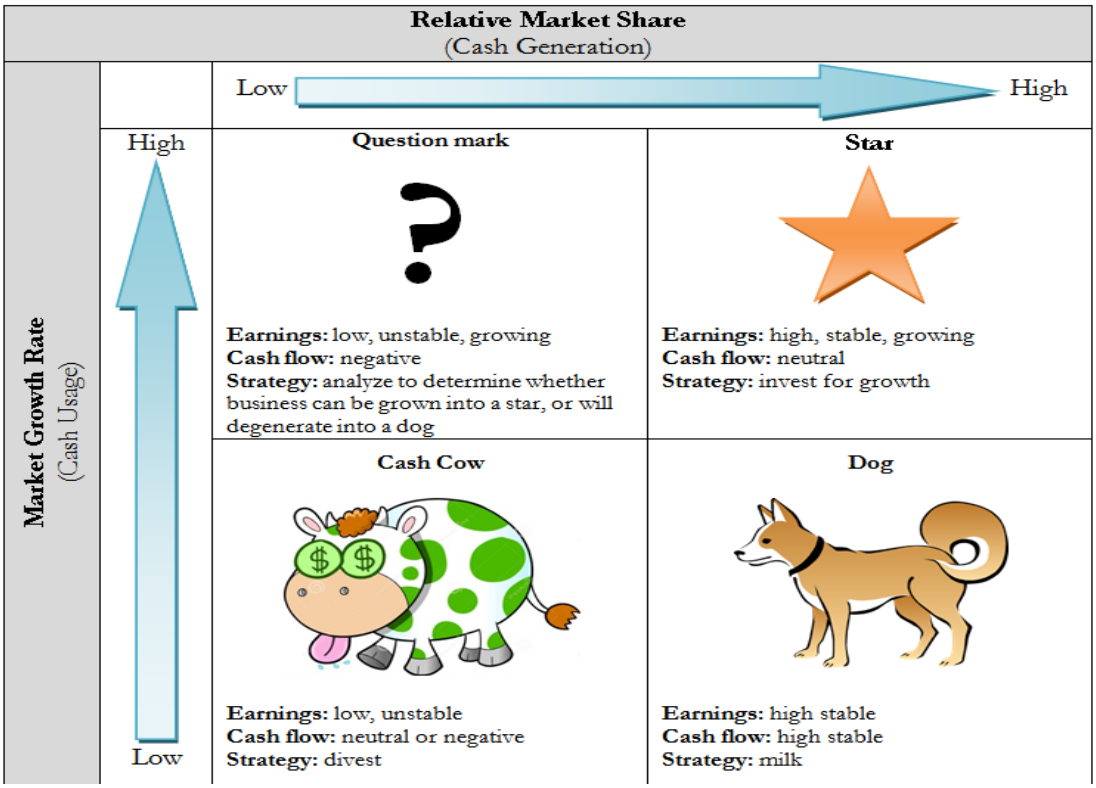


Figure 1. The BCG Matrix

Table 1. The advantages and disadvantages of the growth-share matrix

| **Advantages:** | **Disadvantages:** |
|---|---|
| • provides a framework for allocating resources among different business units;<br>• allows to compare many business units at a glance;<br>• matrix are clear and easy to build; | • model simplifies the complex process of decision-making;<br>• link between market share and profitability is questionable since increasing market share can be very expensive;<br>• approach may overemphasize high growth, since it ignores the potential of declining markets;<br>• matrix considers market growth rate to be a given, but in practice the firm may be able to grow the market;<br>• the growth rate of the market can not reflect:<br>○ attractiveness of the sector as a whole because there are many factors affecting it (entry barriers, macro and micro economic factors);<br>○ profitability of the industry, since high |

| Advantages: | Disadvantages: |
|---|---|
| | growth rates and low barriers to entry may occur intense competition, which will make the industry not promising for the company;<br>• the relative share of the market cannot talk about the competitiveness of goods, because it is result of past effort and ensure product leadership in the future; |

### 2.3.2 GE / McKinsey Matrix

The General Electric\McKinsey Matrix - is method of assessing the competitive position of companies on the market or the product portfolio analysis of strategic business units (SBUs), where the choice of strategic decisions depends on the market share, profit margins, the price position of product quality, the efficiency of sales, and the success of the staff image. The scheme of the GE matrix is a quadrant formed by two axes, where the vertical axis - the industry attractiveness and the horizontal axis - is a competitive segment or business strength. Each of them is divided into three parts: low, medium and high (Kevorkov V., 2013). The strategic position of the business improved as it moves from right to left on the matrix from the bottom up. Each quadrant has its own strategy. The matrix is shown on Figure 2. The advantages and disadvantages are represented in Table 2.

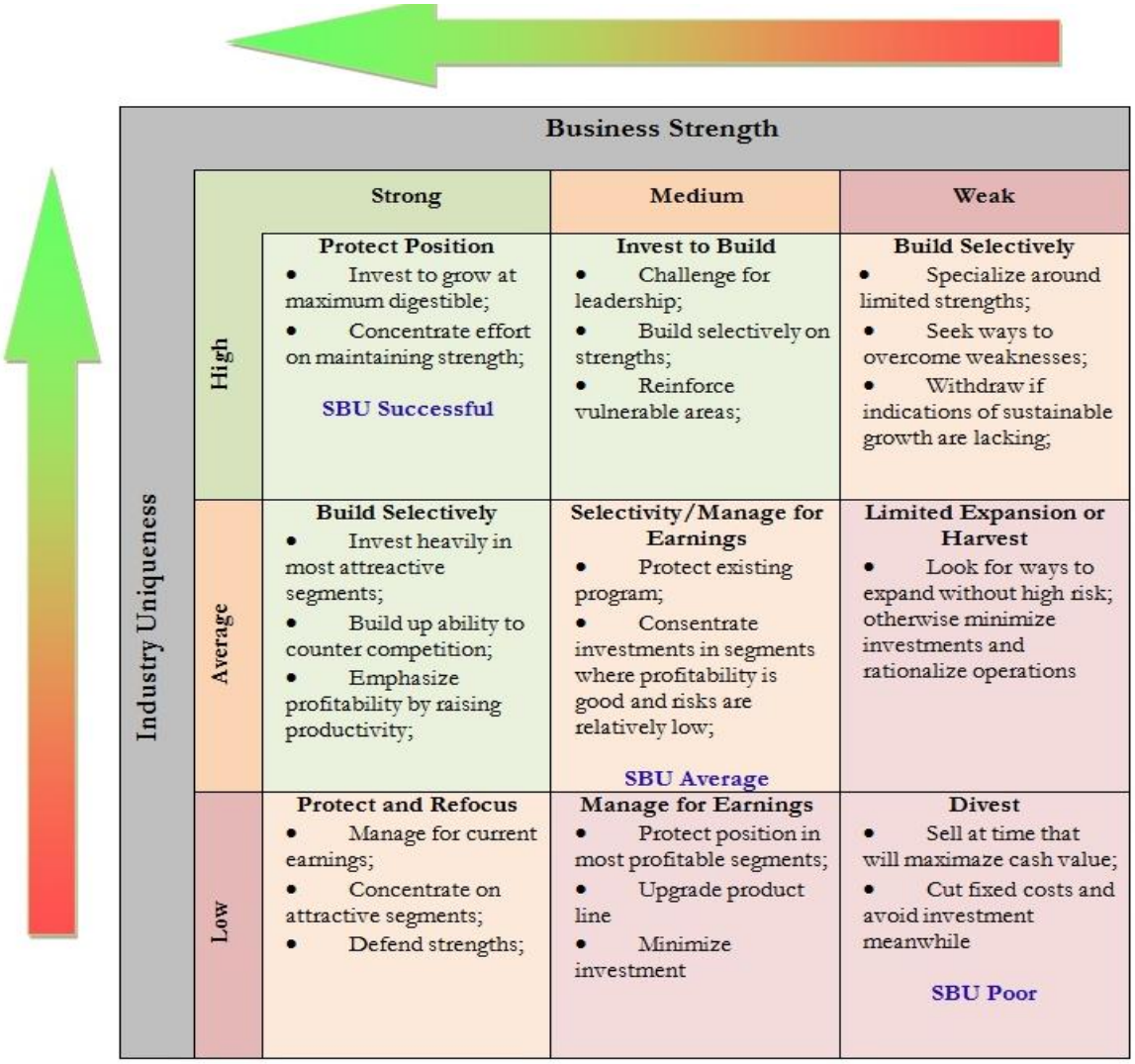


Figure 2. The General Electric / McKinsey matrix

The GE matrix General analysis is carried out on the parameters "strategic business area" and "competitive position" There is three areas of the strategic position (GE matrix):

- Green - Area of "winners" - an area of high potential (three top-quadrants). This is a business that has the best or average compared to other factors of attractiveness of the market value and benefits of the company.
- Orange - Average area or border (three middle quadrants). This is a business, which under certain conditions can either grow and turn into "winners" or shrink and become "losers". Three diagonal quadrants have an average attractiveness.
- Red - Area of “losers” - an area of low potential (three lower quadrants). These businesses that have at least one of the lower and do not possess any of the higher parameters plotted along the axes.

Table 2. The advantages and disadvantages of the GE / McKinsey matrix

| **Advantages:** | **Disadvantages:** |
|---|---|
| • used in the presence of a large number of individual strategic business units and product lines;<br>• can be used at all levels within the company. At the corporate level, the elements of the business portfolio can be analyzed using this matrix. At the level of the business units can be analyzed individual products.<br>• increasing the dimension of the matrix up to 3x3 allowed not only to give a more detailed classification of comparable types of business, but also consider the wider opportunities of strategic choice;<br>• allows us to consider the dynamics of the second factor - the attractiveness of the strategic business areas;<br>• the matrix is a convenient tool to prioritize investing in various types of business and for the reallocation of resources; | • there is a risk that the focus on growth businesses related to the "winners", one day will enter to overloading area of investment resources, which will cease to give the desired effect;<br>• the short term is very difficult to assess the correctness of investments in businesses related to the winners, since the effect can occur much later;<br>• assess of market attractiveness is based on the assumption that it necessarily reflects the average profit potential in the long term for all industry members;<br>• matrix strategies are only recommendations and serve as a reference for further in-depth analysis and cannot be regarded as a management decision;<br>• a breakdown of the matrix axes is controversial:<br>o it does not varies with a change of evaluated factors;<br>o it lost rational core comprehensiveness, than only a few estimates made up the one that determines the coordinates of the position of business on the corresponding axis; |

While the GE business screen represents an improvement over the simpler BCG growth-share matrix, it still presents a somewhat limited view by not considering interactions among the business units and by neglecting to address the core competencies leading to value creation. Rather than serving as the primary tool for resource allocation, portfolio matrices are better suited to displaying a quick synopsis of the strategic business units. (GE/ McKinsey Matrix).

### 2.3.3 Ansoff Matrix

Igor Ansoff presented a matrix that focused on the firm's present and potential products and markets (customers) to portray alternative corporate growth strategies. By considering ways to grow via existing products and new products, and in existing markets and new markets, there are four possible product-market combinations (Ansoff Matrix). Ansoff's

matrix is shown below: (See Figure 3). The advantages and disadvantages are represented in Table 3.

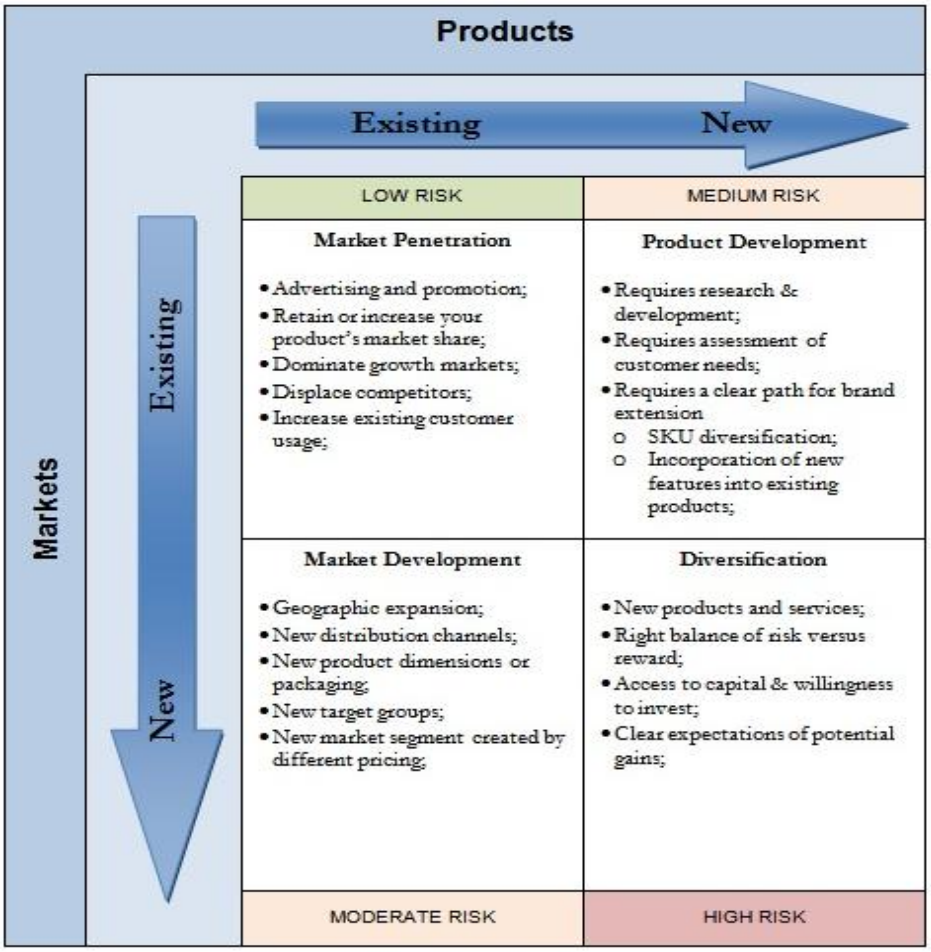


Figure 3. The I. Ansoff matrix

Ansoff's matrix provides four different growth strategies (Ansoff Matrix):

- Market Penetration - the firm seeks to achieve growth with existing products in their current market segments, aiming to increase its market share.
- Market Development - the firm seeks growth by targeting its existing products to new market segments.
- Product Development - the firms develops new products targeted to its existing market segments.
- Diversification - the firm grows by diversifying into new businesses by developing new products for new markets.

Table 3. The advantages and disadvantages of the I. Ansoff matrix

| **Advantages:** | **Disadvantages:** |
|---|---|
| • matrix is a simply graphical toll that allows a business or individual to weigh up a complex situation or decision;<br>• can be used to explore the different directions for strategic growth;<br>• four strategic options can be generically applied to any industry; | • matrix is highly simplistic and does not factor in the external environment, especially within a business context;<br>• each strategy carries a certain amount of risk and involves investments;<br>• cannot be used alone to justify the decision; |

### 2.3.4 Arthur D. Little Matrix

The ADL portfolio management approach uses the dimensions of environmental assessment through competitive position and business strength assessment through industry maturity category. Its application is particularly suited to smaller industrial companies and for strategic business units of large companies (Little, 1980). Each of these dimensions can be dividing into the following categories to better analyze a company and accordingly determine the future strategic actions. Competitive position can be either of the following (ADL Matrix):

- Dominant - the position of a company falls into this category if it is a clear market leader or has a monopoly position.
- Strong - the company might not be a monopoly but definitely has a strong presence and loyal customers.
- Favorable - companies with favorable competitive position usually operate in fragmented markets and no single one controls all market share.
- Tenable - each company caters to a niche segment defined by a product variety or segmented demographically.
- Weak - the company financials are too weak to gain a strong hold in the market and is expected to die out within a short span of time.

According on where SBU lies on the ADL grid, a suitable kit of strategies should be chosen by it to gain competitive positions, greater market share and move to higher stages of life cycle. The matrix is shown below: (See Figure 4). The advantages and disadvantages are represented in Table 4.

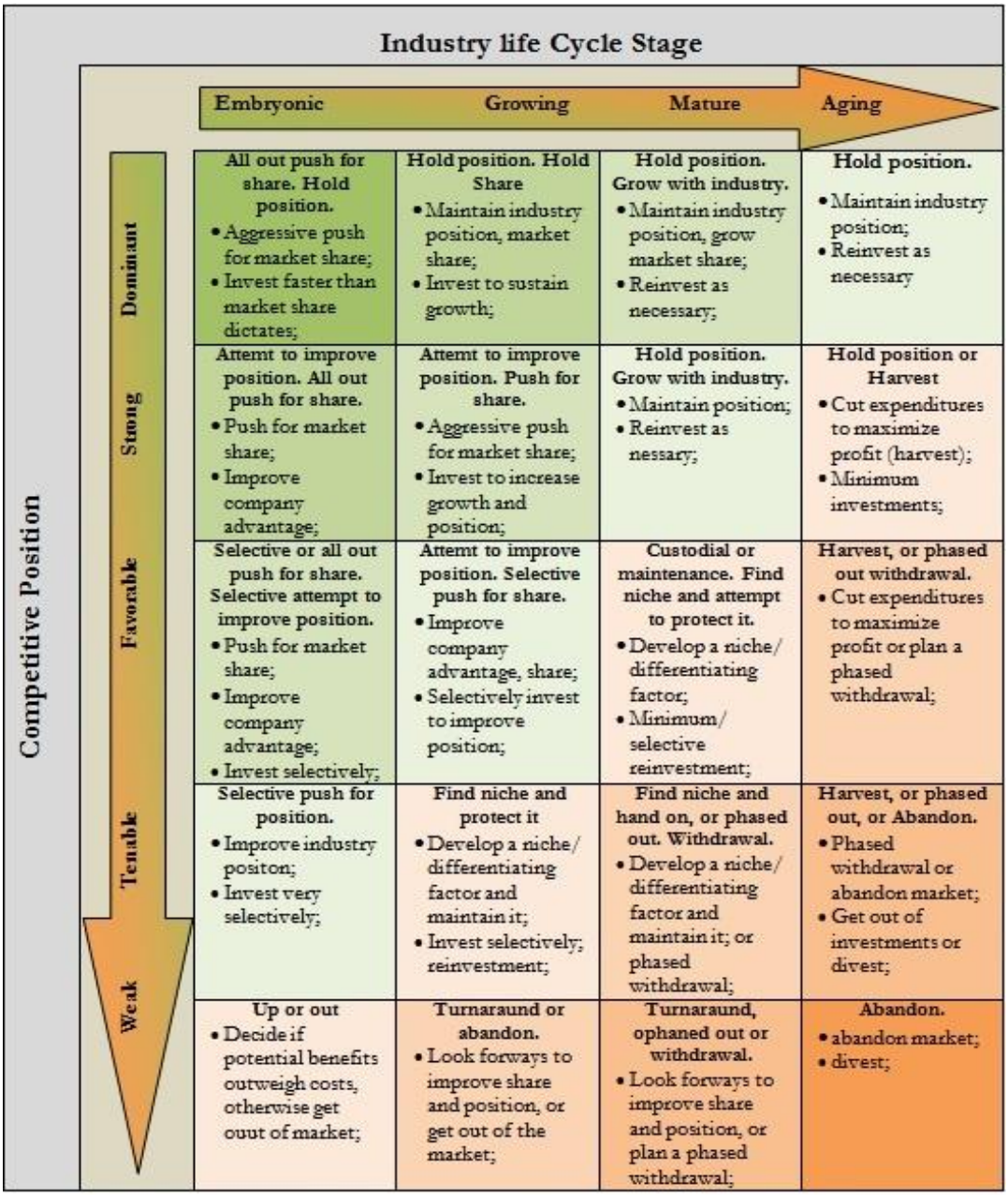


Figure 4. The ADL matrix

Table 4. The advantages and disadvantages of the ADL matrix

| **Advantages:** | **Disadvantages:** |
|---|---|
| • Transparency;<br>• Flexibility in assessing the attractiveness of the industry;<br>• Possibility of balancing a portfolio of production;<br>• Better identification of competition, suppliers, customers, potential substitutes;<br>• Allows to extract the strengths of the prod- | • Excessive empiricism and subjectivity in the application of the criteria for designation of its main dimensions;<br>• ADL is limited to only those strategies that are not trying to change the life cycle, so following the model makes it impossible to develop a strategy that takes into account the situation of such a change.<br>• Theoretical prerequisite of matrix approach |

| Advantages: | Disadvantages: |
|---|---|
| uct portfolio;<br>• ADL approach is especially useful for high-tech industries, where product life cycle is very short and where business cannot achieve their goals if time does not apply the necessary strategy;<br>• Can be applied to the fragmented industries, holding a small competitive advantage but with a large number of ways of obtaining it (provides multiple ways of differentiation). The ADL matrix has a high degree of adaptability to situations of a qualitative nature | is a condition of fragmentary competition in the industry in its infancy, which does not always correspond to practice.<br>• The length of the life cycle might be influence by the competitors of the firm.<br>• Effective planning requires a definite time frame; a rapid change in the industry life cycle can make a chosen course of action obsolete and harm the company's competitive position. |

### 2.3.5 ABC+ZYX

ABC analysis is a common method of studying the range by which can determine the contribution of each product in the store turnover and profit, to distribute products by categories for efficient portfolio management (Combined ABC and XYZ analysis). The advantages and disadvantages are represented in Table 5.

Table 5. The advantages and disadvantages of the ABC analysis

| Advantages: | Disadvantages: |
|---|---|
| • rationalization of the range management makes clear the importance of goods to distribute effort store manager,<br>• quick results and rapid application of administrative decisions;<br>• •if done regularly over the previous period makes it possible to track the stages of the life cycle of products. | • • amount of data needed for analytics during a certain period: the base on checks, sales or other retail data;<br>• if there are any unforeseen situations on market (sharp inflation, political unrest, etc.), these ABC analysis may be inaccurate. |

XYZ-analysis determines the stability of product sales for the period. The results allow to divide the products into categories and to allocate a place for them in the warehouse, inventory levels and delivery organization (Combined ABC and XYZ analysis). The advantages and disadvantages are represented in Table 6.

Table 6. The advantages and disadvantages of the ZYX analysis

| **Advantages:** | **Disadvantages:** |
|---|---|
| • Data management for a variety of goods and inventory management, organization of work with suppliers;<br>• setting of different delivery options for different categories of products;<br>• Use analysis to predict the stability of demand;<br>• determination of the problem with unstable stores sales;<br>• definition of commodity holes, the correction of the supply chain of goods. | • need, as well as for ABC, for stability indicators, without concussions the market;<br>• Necessary data for several years for a full analysis;<br>• difficult to work with seasonal products;<br>• cannot be used on products with short life cycles. |

The combination of ABC and XYZ analysis reveals the absolute leaders (group AH) and outsiders (CZ). If ABC analysis allows estimating the contribution of each product in the sales structure, the XYZ-analysis to evaluate jumps marketing and instability. The results of this analysis can be used to optimize the range, evaluations of profitability of product groups, evaluation of logistics, consumer ratings wholesale company (ABC and XYZ analysis). Matrix is shown in the Figure 5.

| **AX** | **AY** | **AZ** |
|---|---|---|
| High level of income.<br>Stable and predictable consumption<br><br>*Require continuous availability, without the need for excessive safety stock.* | High level of income.<br>Unstable and unpredictable consumption<br><br>*Require an increase in safety stock, as have insufficient stability of consumption.* | High level of income.<br>Accidental and unpredictable consumption<br><br>*Increase stock level entails additional costs of storage. It requires the ability to recharge this product as soon as possible when needed.* |
| **BX** | **BY** | **BZ** |
| Average income level.<br>Stable and predictable consumption<br><br>*Require continuous availability, without the need for excessive safety stock.* | Average income level.<br>Unstable consumption.<br><br>*Require an increase in safety stock, as have insufficient stability of consumption* | Average income level.<br>Accidental consumption.<br><br>*Increase stock level entails additional costs of storage. It requires the ability to recharge this product as soon as possible when needed.* |
| **CX** | **CY** | **CZ** |
| Low income level<br>Stable consumption.<br><br>*Necessary to determine the periodicity of deliveries, in order not to keep an extra items in stock.* | Low income level<br>Unstable consumption<br><br>*Necessary withdraw from circulation unprospective and obsolete products. Requires additional analysis.* | Low income level.<br>Accidental consumption.<br><br>*Necessary withdraw from circulation unprospective and obsolete products. Requires additional analysis.* |

Figure 5. The ABC - ZYX matrix

Using a combined analysis provides a number of additional advantages (Combined ABC and XYZ analysis) (ABC+XYZ)::

- identification of goods with stable sales, significant turnover for the store, and loss of goods;
- increasing the share of profitable products without violating the principles of the assortment policy;
- determining the causes that affect the amount and location of the goods stored in the warehouse;
- redistribution of effort management staff range and inventory.

The matrices can be used to analyze a single product or entire industry. There are no perfect goods and no perfect methods of analysis. Each product has specific properties. Every analysis has advantages and disadvantages. For obtaining an objective analysis of the product portfolio it is necessary to use combinations of matrices. The data allows developing a strategy for each product and management model of product portfolio.

# 3 IMPROVEMENT OF THE PRODUCT PORTFOLIO MANAGEMENT MODEL

The model of management - is not an invention, it is an evolution. (Frederick Taylor)

The evolution of management thought is most clearly reflected in the management models that scientists and specialists develop and then implement in practice with a view to solve the problems. The models themselves are not frozen and can be transformed and converted in accordance with changes in the market. The main task of the manager is to properly integrate all the major trends and adopt the most effective model.

Under the "management model" should be understood set of ideas about how should look the management system, how it affects the control object, how adapts to changes in the external environment. This enables company to achieve its goals, develop sustainably and ensure its viability (The concept, features and functions of management, 2015). The model includes the basic principles of management, strategic vision, targets, values, structure and coordination of its elements, organizational culture, analysis and control, driving forces of development and motivational policies.

In accordance with established practice, a model which the manager seems perfect or the most appropriate can be (Gaponenko, 2003):

- ready-made model, bearing in mind that the global experience of practical management gave a considerable number of methods, which in due time and under certain conditions gave a positive result;
- build a model of the most effective parts and pieces of various management models, using the assembly method;
- choose a basic model of management that meets the requirements, exclude unwanted elements from it, elaborate and build new elements which meet the specific characteristics of a managed object and conditions of its functioning;
- create and launch an entirely new model based on a new paradigm, able grasp the emerging changes in the external environment, which will become dominant in the future.

The optimal use of the available production and financial resources for maximum compliance of products range demands of consumers is a condition for enterprises' development. The main task of the portfolio management is the optimization of financial results of enterprises' activities.

Features of the Russian market influence on the formation and management of product portfolio. The following peculiarities can be distinguished:

- Russian manufacturers are not "trendsetters" for the majority of products, but are manufacturing products "looking like" imported analogues;
- one group products, having different trade names, have got different competitive positions in the market (the difference in price and the life cycle of a branded product can differ from the analogue in several times);
- enterprises lack internal resources for the timely and adequate reaction to market changes;
- certain market trends or restrictions (state regulation etc.) in the market segments.

Volumes of production costs depend on the product range selection. The nomenclature curtails by 50% increases the production capacity by 30%, reduces costs by 17% and decreases the breakeven point. When the product range extends by 50%, costs are increased by 20–35% per production unit. The excess product range reduction causes the drastic decrease of sales due to the lack of products, being of consumers' demand (Kevorkov V., Product Portfolio Management of the Company, 2013).

Solving the problem of product portfolio management, the company solves the problems of costs, load of production capacities and sales, and profits.

## 3.1 Development of the offers for detailing product classification

The product portfolio is the integrity of total products (groups of products, kinds and species of products), which can be manufactured within frames of organizational, economic and technologic conditions of such production (manufacturing with the same park equipment). Practically, the portfolio is integrity of products, having different profitability level and undergoing different life cycle stages, and, as a consequence, having different market prospects. Due to the different life cycle continuity the portfolio composition is

variable, what is stipulated by the withdrawal of old products and mastering of new ones (portfolio rotation). Its composition and structure should meet the integrity of different goals of the enterprise planning.

The product portfolio management is a sophisticated process, meaning the selection of the optimal solution, while taking into consideration all possible optimization criteria and restrictions, taking place in existing and possible conditions while implementing different development alternatives. Depending on the kind of tasks, for which achievement of the portfolio structure is oriented, as well as on the time period, within which it is planned to achieve target indices, different types of products' classification inside the portfolio can be applied. Formation the product portfolio was based on the fact, that for each product, consumers' needs are to be determined, e.g. the total of features, describing certain product consumers in detail. Consumers should treat the product equally from the point of view of its discovered merits, apply it in a similar way and to react likewise to instruments of marketing activities (price, advertising etc.), to demonstrate the likely behaviour, as well as the loyalty to the product. In this case, depending on their value system, consumers and, accordingly, products, will be grouped in separate groups. It proposed to introduce the concept of "product level" and to create the products' classification by levels. For the product portfolio it is necessary to determine the hierarchy of analysis levels. It offered to establish the products' hierarchy. For classification purposes used such notion as "strategic business unit (SBU)".

**The first level product** is a strategic business unit (SBU) – an organizational unit, responsible for the development of the company strategy in the target market. It has market purpose, an independent development trend or a company subdivision, a mission, its own products' lines, specific competitors and its own sales markets. For example the first level product can be considered as business trend or a group of products.

**The second level product** is a strategic business unit (SBU) – an organizational unit, responsible for the development of the strategy in the product line. It has own market target, an independent development trend, specific competitors and own sales markets. For example the second level product can be considered as product line inside a group of products.

**The third level product** is a strategic business unit (SBU) – an organizational unit, responsible for the development of the strategy for one or several products or kinds of goods, satisfying alike needs, occupying a certain position in the market segment and having common production and promotion peculiarities. The third level product is a kind of product, which can comprise different kinds of package, sorting and dosage. Typically, such product has got a trade mark (brand). Several third level products make a second level product.

Provided peculiarities of such classification for each level product offered to use different strategies (short term or long term), monitoring periods, as well as the financial evaluation of changes. In such case the portfolio analysis is used for the analysis of the relevant level product. Strategic business units are being analyzed in total, provided optimization criteria and restrictions allow revealing key operations. The application of such a classification allows simplifying the product portfolio analysis at the expense of reduction of the quantity of analyzed products.

Most companies having different product range, financial capacities, working in different markets. They use product portfolio analysis methods to form the strategy, oriented for long-term goals. The main shortage of such analysis is that the current status data cannot always be extrapolated to the future, or it can cause an error. The application of levels classification allows obtaining more authentic data.

Each enterprise has got its own sales' profile. There are product portfolios where 2 products are dominating. There are also a few with 5-6 denominations. The analysis is based on structuring the product portfolio by three levels:

- 1st level – a group of products. At this level the product portfolio is divided into groups of products with same designation/trend, having its own market. Market changes are being analyzed in whole, as well as selected segments.
- 2nd level – product line. These are substitute products from one group. At this level the products are consolidated into substitute products' group. The company's product groups are compared with groups in the market and analyze how they change.
- 3rd level – enterprise products. This level comprises all products, manufactured by the enterprise nowadays. Each product satisfies a certain need and it may have several SKU (Stock Keeping Unit).

## 3.2 Development of the management algorithm

As a rule, the product portfolio comprises three levels of products. Depending on target planning goals, products from three levels can be used, or products from different levels can be combined. Each level has got products, located at the certain lifecycle stage, and occupying leading, neutral or underperforming positions.

The first level product (group of products) has got a life cycle, including conceiving, growth, and substitution of weak players, maturity and extinction. Usually it is compared with a branch life cycle. In relation to the branch life cycle products can be obsolete, new, innovation. At this level both internal and external environment factors are being analyzed. Among external factors the important role belongs to market attractiveness, its volume, dynamics, maturity, saturation, elasticity, peculiarity and market admission price, influences of state authorities, consumers' preferences.

It is recommended to analyze the enterprise with SWOT method before the analysis, in order to be aware of the current enterprise situation, its opportunities and threats. According to G. Inozemtsev (2005) for first level products the long term planning (2-5 years) is strategically important. For the analysis of such product it is recommended to use BCG matrix or to use the combination of SWOT-analysis and General Electric / McKinsey matrix. Having analyzed external macro- and micro-factors of the business environment, as well as of internal strong and weak point of the product level, will be reveal key figures of the success and main strategic problems, for which we need to preview mandatory changes and activities in the following action program (Inozemtsev, 2005). If it is necessary to extend the existing product portfolio to increase the sales, as well as the market share in the first level, it is possible to additionally do the PEST analysis. By results of analysis of the first level products strategic decisions can be made, as offered by the used matrix.

The second level product is an independent trend of product lines' development at one of target market segments. To analyze such products it is necessary to evaluate growth possibilities between existing products and existing markets, new products and existing markets, as well as new products and new markets. It is also necessary to analyze specific competitors, technological trends, substituting products and consumers' demands. At this level both internal and external environmental factors are being analyzed. Among external factors the important role belongs to the breadth of the market, its maturity, saturation,

competitive environment, and consumers' demands. Among internal factors the main role belongs to the innovative technological component. According to Inozemtsev (2005) for second level products it is important to use long-term strategies (2-5 years), as well as short term tactic solutions (1 year). In the analysis of product should be used Ansoff matrix. For more detailed strategy development recommends to use ADL matrix. It allows planning product or service strategy in conformity with the life cycle stage of the branch, as well as with the level of competitive ability of the company in the market. ADL matrix allows determining the long-term development vector for the company and the product.

Having analyzed external macro- and micro-factors of the business environment, as well as internal strong and weak points of second level products, will be found out:

- the level of the market penetration;
- what are opportunities for the product development;
- what are opportunities for extension of the product market share;
- diversification opportunities.

Based on the results of the analysis of the second level products it is possible to make strategic decisions, offered by used matrices.

The third level products consist of all the product names, manufactured by the enterprise at the present time. The portfolio analysis of these products evaluates the actuality of company products, depending on the growth of production market and the occupied share. The third level product is considered from the point of view of its promotion in the market. The life cycle of product comprises its launch in the market, growth, maturity and extinction. Such conditions require long term and short term tactic solutions. For this purpose ADL matrix will be suitable. In the interest of more detailed analysis BCG matrixes are used or additional analysis of statistic data. In the analysis of the product range inside the third level, methods of assortment analysis can be applied: ABC, ZУX, ABC+ZУX.

The algorithm of the model of the product portfolio analysis:

- analysis of the enterprise product portfolio
- differentiation of the product portfolio into three levels. Group of products (the first level product is considered as business trend or a group of products). Product line (the second level product is considered as product line inside a group of products). Kind of product (the third level product);

- collection and analysis of statistic data;
- selection and building of the product matrix;
- selection of product strategy;
- confirmation of the selected strategy and additional research;
- implementation of the selected strategy and determination of control periods

The algorithm includes several levels of decision making:
First level of decision making – making of the decision on the product's prospective (group of products) includes:

- evaluation of the market potential includes evaluation of the economic situation, analysis of the market volume, structure and dynamics, determination of financial channels and of its prospects, analysis of market development trends, determination of the market capacity;
- evaluation of the product potential includes evaluation of the competitive environment, evaluation of development prospects of the competitive environment;

Second level of the decision making – development of the marketing strategy for the product (product line) launch to the market. It consists of:

- evaluation of the product potential includes description of the existing application practice, determination of purchases' process, product positioning, determination of the optimal price.
- determination of the consumption potential includes segmenting and targeting of target audiences, determination of optimal promotion channels.

For the third level products the second level of decision making is applied.

## 3.3 Analysis of the optimization results of the product portfolio management model

Matrix, described in the second chapter, can be used for the analysis of all products levels. In order to obtain unbiased analysis results for each product it is better to use two matrixes, as following items are of importance: market changes, product changes, competitive environment changes, change of the enterprise itself.

For the optimization of the management strategy, applied for the third level product, it is recommended to analysis the first and second level products, comprising the third level product. In order to develop the analysis inside the third level product following product range analysis methods can be applied: ABC, ZУX, ABC+ZУX. Due to such algorithm of the portfolio analysis, select whole strategic trend, strategy of product lines development and product development strategy.

The developed method was tested on the example of a pharmaceutical company. Using this algorithm must take into account characteristics of the product and the market.

In the pharmaceutical market for the consumer does not matter taste, color and smell of the product. His choice is based on a doctor's recommendation. However, if the product is effective, then the consumer will come again.

Next, consider the other factors influencing the formation of the portfolio.

# 4 THE PHARMACEUTICAL INDUSTRY IN RUSSIA

The pharmaceutical market in times of crisis and sanctions is the most stable segment of the economy, as its quite strong social component. Traditionally, the pharmaceutical market is one the most profitable markets both in Russia and abroad. The Russian pharmaceutical market ranks second in volume terms after the foodstuff market and is one of the most dynamic and promising specialized markets. Being mostly domestically oriented, the pharmaceutical market is less sensitive to exchange rate fluctuations than export-oriented industries and is quite stable. Another factor that positively influences its development is that the demand for pharmaceutical products does not strongly depend on the business cycle phase (AstonConsulting, 2012).

According to the State Statistics Committee in 2014 drugs took about 2, 0% in the basic structure of consumer spending in Russia, which is higher by 0.1% than in 2013. Thus, the Committee has slightly increased importance of drugs in consumer spending. Figure 6 shows the general consumer price index and price indices for certain categories of goods and services. The general index of consumer prices in 2014 amounted to 11.4%. At the same time the largest price increase was observed for food (15.4%). Least of all prices increase for gasoline (8.9%) and non-food products (8.1%).

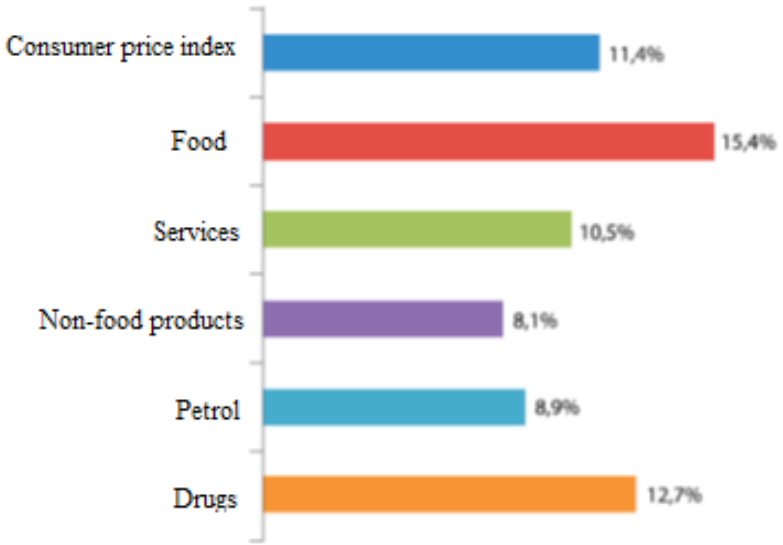


Figure 6. The consumer price index in Russia (December 2014 to December 2013)

## 4.1 The specificity of the pharmaceutical industry in Russia

The pharmaceuticals' market is a part of consumer goods and services market; it has он имеет следующие особенности got certain peculiarities, influencing its organization considerably. It has the following peculiarities:

- broad product range of pharmaceuticals;
- long term cycle of pharmaceuticals' development;
- high research intensity;
- huge variety of technological processes, kinds of equipment, raw and other materials, used for the manufacturing of pharmaceuticals;
- often amendments, extensions and renewals of the manufactured production;
- manufacturing generics;
- demand dependence on epidemics, natural disasters and other emergency situations;
- trend for world globalization.

The world globalization trend is stipulated by certain factors. All people need to protect and reinforce their health, aiming to prolong the life period. In different countries the dynamics of disease incidence, pathological and physiological mechanisms of diseases are similar. The high cost of development and implementation of new pharmaceuticals, requires joint efforts. Scientists need to exchange innovative technologies, as well as results of scientific & research works. Pharmaceutical companies tend to merge in order to capture a larger market share. There are common international standards for the manufacturing (GLP, GCP, GMP), distribution and pharmaceutical practice (GDP, GPP), storage and transportation of pharmaceuticals (DSP).

Pharmaceuticals market structure – this is a system of mutually related and interacting production subjects and objects, distribution and consumption of pharmaceuticals.

Subjects of pharmaceutical market are management and regulation authorities, production, distributors and pharmacies, specialized information & analytic editions, agencies, consulting companies, professional public organizations and consumers.

Consumers of pharmaceutical production – is a sophisticated sub-system of pharmaceutical market subjects, having different motivations for the consumption of pharmaceutical

products, different values for its purchase, different methods, designation and process of consumption. They are divided into following types:

- prevention and treatment facilities;
- wholesale and retail drugstore establishments, pharmaceutical companies;
- final consumers, their family members, using products for personal or family consumption;
- intermediate consumers – health workers (physicians), administering the substance for the purpose of its use within the hospital or prescribing a medicine to be used by outpatients.

The pharmaceutical market of final consumers is segmented by different methods and in conformity with different criteria. The most common are demographic criteria (sex, age, and family membership), geographic criteria (district, residential density), social & economic criteria (income level, education), psychological criteria (life style, personal characteristics).

There are following types of consumer behavior: super-innovators (3%), followers, majority, super-conservatives – people speaking against any changes (11 – 15%). It is based on consumers' division depending on purchases' motivation, consumption intensiveness and attitude to production: For example:

- tried to apply a pharmaceutical – single time, repeated, frequent user;
- generic user (price is selection criteria);
- user adherent to a certain pharmaceutical (the selection criteria is confidence).

One of the most important factors for end-user segmentation for prescription drugs is the behaviour of the doctor when he prescribed the medication. The interaction of physicians, pharmacies and patients can be schematically presented on Figure 7

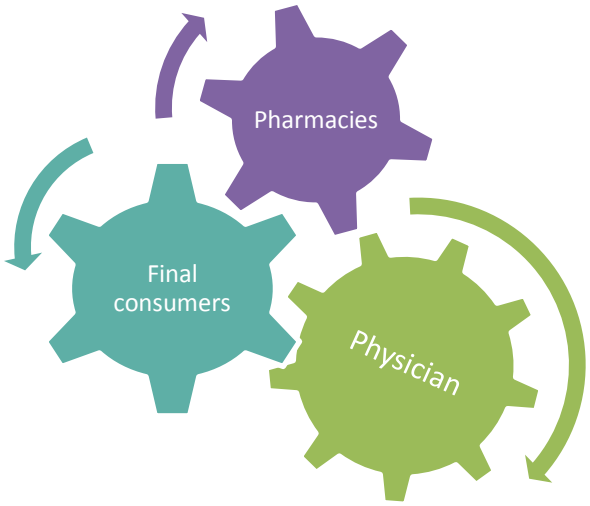


Figure 7. The interaction between physicians, pharmacies and patients

Pharmaceutical market objects are pharmaceutical products (pharmaceuticals and health products), services, information, customer "tastes" (needs), production quality, technologies.

The sales structure of the pharmaceutical market divided to commodity and consumer groups. The medicines on the market are divided into prescription (Rx) and non-prescription (OTC) drugs.

The modern Russian pharmaceutical market regulated by Federal law on circulation of medicines (2010). All authorized medicinal products included in the State register of medicines. The domestic manufacturers mainly produce generic medicines. The imported medicines take a significant market share. The advertising of Rx drugs in the media is banned (Law, 2006). The federal target program: "Development of Russian pharmaceutical industry for the period up to 2020 and future outlook" is aimed to support domestic producers. In conditions of crisis 2014 - 2015 an increase in sales in rubles and fall in packages. This is due to higher prices for imported medicines.

## 4.2 Main segments of the pharmaceutical market

The pharmaceutical market of Russia in the structure of sales can be divided into two main segments, which are divided into sub-segments. The structure is shown in Table 7.

Table 7. Segmentation of the Russian pharmaceutical market

| Segment | Sub-segment |
|---|---|
| **Commercial (retail) segment:**<br>• anxiety occupies 60 - 70% of the market;<br>• include prescription (RX) or non-prescription (OTC) drugs;<br>• assigned by a doctor or recommended by a pharmacist or chosen at the patient's own discretion;<br>• all medication purchased by consumers (patients) in pharmacies | **Pharmacy para-pharmaceuticals segment:;**<br>➢ non-medicinal products;<br>➢ for sale no license or special permission is required (i.e. cosmetics, bio-active biological additives, personal hygiene products, etc)<br>*This segment is not included in the case study.* |
| **State-owned segment:**<br>• occupies 30 - 40% of the market;<br>• include only prescription (RX) drugs;<br>• all medication purchased by state;<br>• free of charge for the patients. | **Hospital segment:**<br>➢ occupies 15 - 20% of the market;<br>➢ medication and the other items intended for meducal use;<br>➢ purchased by medical facilities for internal use or for outpatient treatment for certain categories of patients;<br>➢ The main document regulating this segment:<br>✓ The Vital Drug List (**VDL***);<br>✓ Governmental medical care guarantee program;<br>✓ Standards and procedures of medical care; |
| | **Reimbursement segment:**<br>➢ occupies 20 - 25% of the market;<br>➢ provides certain medication to an eligible category of patients using government funding<br>➢ Divided into two major sections:<br>✓ drugs purchased according to centralized system which using federal funds for the treatment of patients suffering from 7 high-cost nosologies;<br>✓ drugs purchased under the PVD (Provision of the Vital Drugs) program by each region. |

The Vital drug list (VDL) contains essential medications that reduce mortality and morbidity within the population. VDL is a guarantee that the government will provide the most essential drugs to its citizens (i.e. sufficient supplies of drugs in pharmacies and medical facilities as well as affordable prices for all consumers) (AstonConsulting, 2012).

Currently the Vital drug list contains 608 INNs including 67% that are manufactured domestically (State Register of medicines, 2015).

The State register of medicines, the Vital drug list and other specialized directories take into account the classifications of medication.

## 4.3 Classifications of medication

There are two classifications of goods used in the pharmaceutical market (State Register of medicines, 2015):

- the Nosological Classification (ICD) indications of the pharmaceutical drug" (therapeutic effect);
- the Anatomical Therapeutic Chemical (ATC) Classification System (pharmacological effect)

Nosological classification, i.e. groups of diseases or indications for use of medicinal product, takes into account the medical practice. There is an International Classification of Diseases (ICD), which describes the 22 class of diseases (WorldHealthOrganization) (State Register of medicines, 2015). The classification is available on the World Health Organization website.

Each class has its own subclasses of disease. For example, a Class IX: Diseases of the circulatory system includes heart disease (OCH, DCS, IHD and others), diseases characterized by high blood pressure and others. For example Class XI: Diseases of the digestive system has subclasses diseases of the oral cavity, diseases of the esophagus, stomach and intestines, liver disease and others (WorldHealthOrganization).

Some classes of diseases have similar causes, symptoms, conditions, as well as similar methods of diagnostics and laboratory analysis (blood, urine, etc.). For example, Class V: Mental and behavioural disorders and Class VI: Diseases of the nervous system.

The same principle used for training and specialization of physicians: therapy, cardiology, neurology, gastroenterology, oncology, obstetrics and gynaecology and other infectious diseases.

The market classification by pharmaceutical drug indices is based on a certain group of symptoms: (e.g. cold, headache) or on a certain disease treatment (e.g. gastritis). This kind of classification is oriented to the customer, as both the physician and the patient refer symptoms to a certain disease. The disadvantage of this classification is that it does not take peculiarities of medical practice into consideration. A physician can select drug from different pharmacological groups for the treatment of a same disease.

The classification of disease is referred to the first level of ATC classification, where medications are distributed by kinds of nosological or pharmacological groups. The market classification by pharmacological groups provides the data for pharmaceuticals' sales by pharmacological groups. ATC classification is carried out by World Health Organization Centre (WHO) collaborating centre for drug statistics methodology in Oslo, Norway. Adopted by the Health Ministry of the Russia (State Registry of Pharmaceutical Drugs, Health Ministry of the Russia, Moscow, 2002) (State Register of medicines, 2015) (ATC classification). The main therapeutic classification group are presented (first classification level) in Table 8.

Table 8. First level ATC-classification

| **ATC groups of I level** | |
|---|---|
| **Code** | **Content:** |
| A | Alimentary tract and metabolism |
| B | Blood and blood forming organs |
| C | Cardiovascular system |
| D | Dermatologicals |
| G | Genito-urinary system and sex hormones |
| H | Systemic hormonal preparations, excluding sex hormones and insulins |
| J | Antiinfectives for systemic use |
| L | Antineoplastic and immunomodulating agents |
| M | Musculo-skeletal system |
| N | Nervous system |
| P | Antiparasitic products, insecticides and repellents |
| R | Respiratory system |
| S | Sensory organs |
| V | Various |
| ~ | Medicaments, without ATC-group |
| A | Alimentary tract and metabolism |
| B | Blood and blood forming organs |
| C | Cardiovascular system |
| D | Dermatologicals |
| G | Genito-urinary system and sex hormones |
| H | Systemic hormonal preparations, excluding sex hormones and insulins |

These classifications are used by all subjects of the pharmaceutical market. The market is valued according to the number of packages (i.e. in units of consumption goods) and in terms of cost. It is also estimated by product names, groups (based on ICD and ATC), the segments (OTC and RX drugs), and so forth. The joint analysis of both indicators gives an idea on pharmaceutical market trends.

## 4.4 How new method of product portfolio analysis will work with pharmaceuticals classifications?

During the development of a new method of portfolio analysis were used ATC and ICD classifications. Thus the portfolio will be altered in way, that all types of doctors and costumer will be able to use and to understand it. Application of both classifications demonstrated on the example of blood circulation diseases. (See Figure 8)

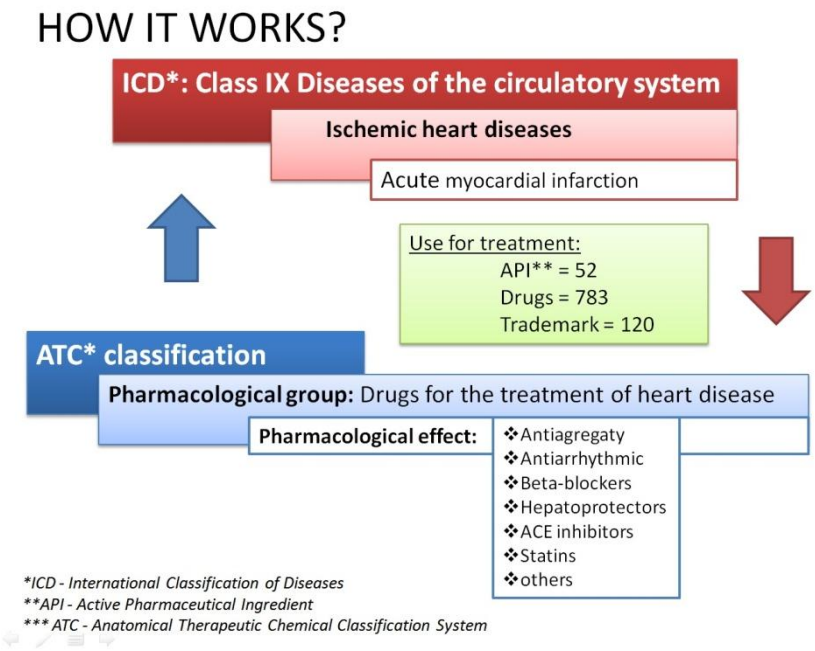


Figure 8. How ICD and ATC work together on the example of cardiovascular diseases

For example on the International Classification of Diseases IX Class - are diseases of the circulatory system which includes groups, including ischemic heart disease (first level product). Groups are divided into subgroups such as ischemic heart disease is divided onto acute myocardial and etc (second level products). Used for treatment 52 API (corresponding INN), including 783 drugs, including 120 trademarks (third level products). All these medicaments divided by ATC classification. In the ATC classification exist pharmacological group, which includes drugs for heart diseases treatment that are actually divided into subgroups. Thus, when forming the first level product use ICD. When forming the second level product use ATC. When forming the third level product use INN - The international non-proprietary name.

Features of market segments, customers, and classifications of medications should be considered in the formation of a pharmaceutical company's product portfolio. Matrix methods can be applied to the analysis of specific products (third level product) and/or pharmacological groups (second level product) and/or groups of diseases (thirst level product). For example, such diseases as whooping cough and poliomyelitis are gone and and significantly decreased the market share of the vaccines. They moved into the category of dogs. At the same time has increased the market share occupied by immunological drugs. Now they are "cows" in the portfolios of pharmaceutical companies. Among the pharmacological groups appeared new group - statins (to lower cholesterol). They actively take market share of cardio. Innovative companies to optimize the portfolio work only with drugs for the treatment of one group of diseases (oncology) or one pharmacological group (antibiotics). Generic companies are trying to work with several groups of drugs.

Analysis of the current situation on the Russian market is presented in Appendix1.

The volume of Russian pharmaceutical market compared to other countries is presented in Appendix 2.

## 4.5 Forecast of the Russian pharmaceutical market

The Russian pharmaceutical market had a positive trend in 2015.

Forecasts of the Russian pharmaceutical market development are quite positive. The market grew by 15% in rubles and equal to 1.3 trillion rubles (DSM Group). Forecasts of market growth are shown on Figure 9.

Despite the positive growth forecasts for the Russian pharmaceutical market, experts believe that the crisis in Russia has just begun. According to Sergei Davydov, a business consultant and main partner of Management Centre Europe (Brussels), the factors that led to the crisis, has not yet disappeared. These factors are including (Davydov, 2015):

- Internal factor:
    - inefficient oil and gas dependent economy;
    - labour productivity remained at the same level as many years ago, 25% of the US level, and wages rose more than 10 times;

  - oil and gas revenues constitute about 50% of the income of the federal budget;
  - low investment attractiveness (in 2015, the international rating agency Standard & Poor's downgraded the credit rating of Russia to the level «BB +»);

- External factor - sanctions.

Forecasts by Russian Association of Pharmaceutical Marketing (2015):

- fall of the market in packages and in the currency value;
- reducing the level of margin and overall profitability of the majority of participants;
- restriction on the price increases according to the level of the rubles fall to the sharp decline of purchasing power of the state and the population;
- potential difficulties in the supply drugs from the VDL list because of fixing prices in rubbles (which means that their cost will be higher than the sale price);
- the relative benefits for local producers.

All these factors need to be considered in the management of product portfolio.

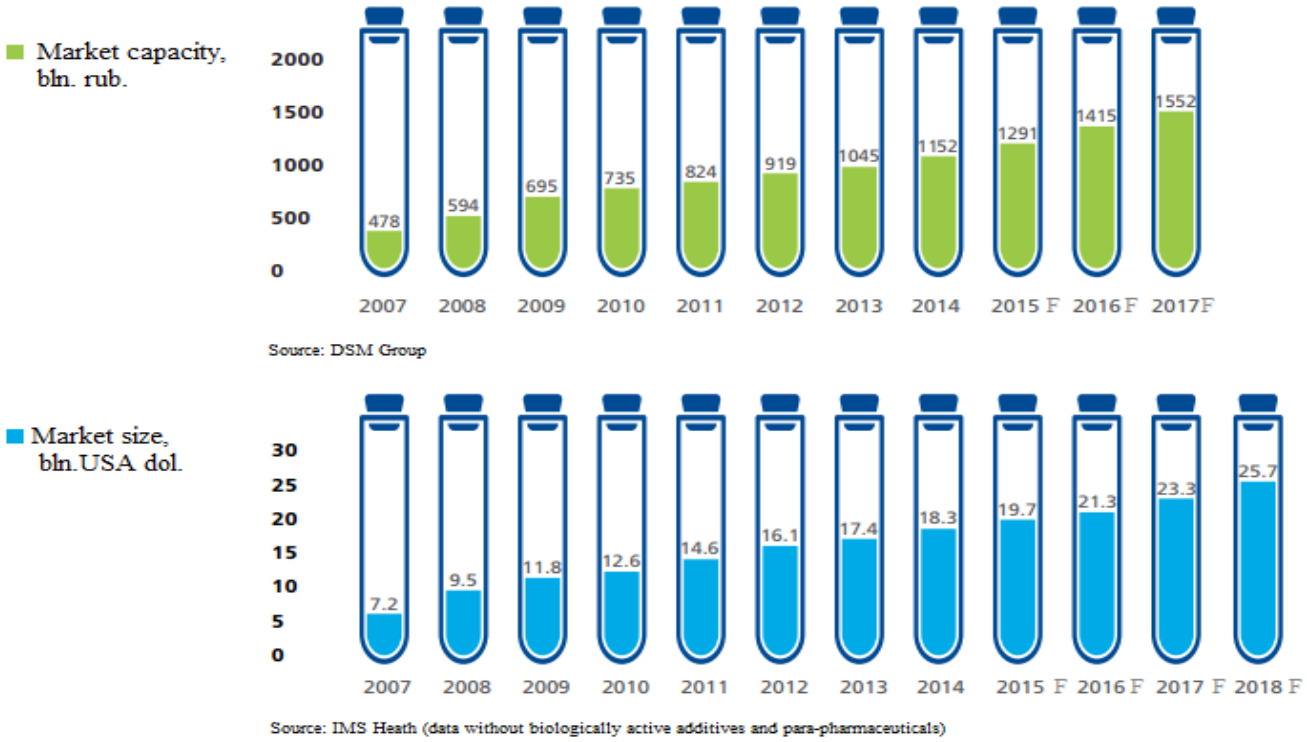


Figure 9. Forecast of the capacity and size of the pharmacological market in prices of final consumption in bln rub. and bln USD (Berezin, 2014)

# 5 CASE STUDY: ANALYSIS OF THE ZAO «SEVERNAYA ZVEZDA» PRODUCT PORTFOLIO

ZAO "Severnaya Zvezda" is dynamically developing pharmaceutical company. It exists in Russian market for more than 19 years. This is a modern manufacturing facility of ready-made pharmaceutical products equipped in accordance with GMP international standards (See Appendix 3). The enterprise carries out its activities on the basis of License of the Federal Service for Supervision in the Field of Health Care and Social Development No. 00003-ЛС-П dated 14.02.2014 "For Carrying Out Drug Manufacturing Activities" (See Appendix 4).

Purpose of the enterprise is to provide high quality, appropriately priced products to the people, ensuring high profitability and competitiveness of the manufactured finished dosage forms (tablets and capsules). All manufactured drugs are divided into the following classes regarding their pharmacological activity:

- cardiovascular drugs,
- neurological drugs,
- gastrointestinal drugs,
- antiallergenic drugs;
- other drugs.

In total there are 66 positions of drugs in accordance with the data of the State Register of Drugs of the Russian Federation (See Appendix 5). As of 2014 ZAO «Severnaya Zvezda» manufactured 38 drugs: the list includes 361 SKUs, 6 brands, 12 umbrella brands, 20 INNs. The product portfolio is formed on the basis of specific market needs within the relevant period.

The investigation of manufacturing and products sales from 2012 to 2014 was performed for the product portfolio analysis. Information for product range analysis were provided by the company. On customer request this information is confidential.

## 5.1 Analysis of manufactured products by years

In 2012, the list of products manufactured comprised 20 positions of drugs: 38 SKUs. There were neither brands nor umbrella brands among them. The positions included 20 INNs: 38 SKUs. The products were manufactured and promoted under the INN concept. (See Figure 10)


Figure 10. Appearance of products, 2012

The main trend of 2012 was the renewal of the product range:

- market launch of three new drugs, namely Pirazinamide tablets, Ribavirin capsules, and Methotrexate tablets (4 SKUs);
- adding new dosage forms;
- adding new SKUs;
- expelling of SKUs that are of no demand from the portfolio.

In 2013, the list of products manufactured comprised 19 positions of drugs: 38 SKUs (See Figure 11). There were 2 brands (5 SKUs) and no umbrella brands among them. The positions included 17 INNs: 33 SKUs. The company performed rebranding of the package design and started working over creation of the new information image of products for the purpose to improve brand awareness and trust of consumers, as well as to form loyalty to the company. The following range of measures for improvement of the quality of products was taken: prolongation of terms of expiration, use of package materials of higher quality.


Figure 11. Appearance of products, 2013

Trends of 2013:

- low-income product positions were excluded: Verapamil 40 mg tablets, Carbamazepine tablets, Loperamide capsules;
- participation in governmental procurements (Pirazinamide);
- SKUs of no demand were expelled and new SKUs were added;
- product range was reviewed: one drug was launched in 3 dosage forms (3 SKUs);
- branded drugs appeared in the product portfolio of the company (Triducard tablets and Ursodez capsules);
- development of new products and promotion strategies;
- mastering of new niches (the pharmacological group of Statins);
- struggle for quality.

In 2014, the list of products manufactured comprised 25 positions of drugs: 60 SKUs (See Figure 12 and Figure 13).There were 5 brands (9 SKUs), 4 umbrella brands (15 SKUs), and 16 INNs (34 SKUs) among them. The ZAO «Severnaya Zvezda» used umbrella branding for the first time to improve the competitiveness of products. The company started to use ”Forte” products to increase market share. Forte means that the drug has a high concentration of active ingredient and prolonged effect.

Trends of 2014:

- low-income product positions were excluded: Omeprazol capsules;
- contract for manufacturing of Loperamide capsules for the CIS countries was re-started;
- participation in governmental procurements;
- SKUs of no demand were expelled and new SKUs were added;

- product range was reviewed: expelling of 5 names (12 SKUs);
- increasing of the share of branded drugs in the product portfolio of the company (Korsavin, Pikogam, Allerfex);
- emergence of umbrella brands in the product portfolio of the company (Amiodaron-SZ, Ramiprilum-SZ, Ribavirin-SZ, Simvastatin-SZ).;
- development of new promotion strategies and 6 names of new products;
- mastering of new niches (the pharmacological group of psychotropic drugs);
- struggle for quality.


Figure 12. Appearance of products, 2014

After performance of analysis of products for 2012 to 2014, a number of manufacturing names were revealed that were suspended in connection with changes to market conditions. The commodity stocks are available at warehouses of the manufacturer, distributors, and in the retail chain (See Figure 13).

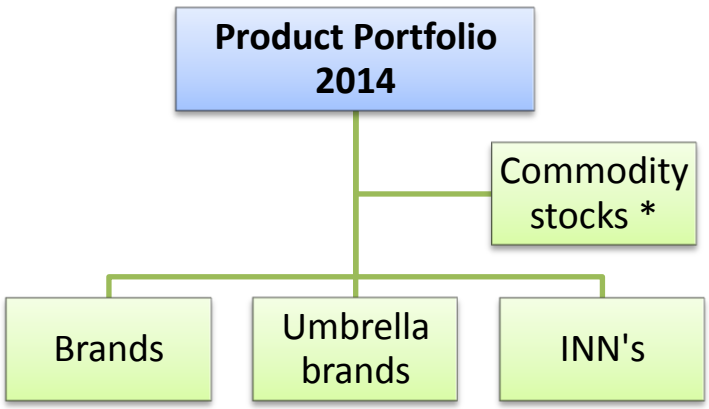


Figure 13. The product portfolio view, 2014

Availability of products in portfolio with different way of promotion(brand, umbrella brand, INNs) led to the need of restructuring of the portfolio.

## 5.2 Development of the new product portfolio management model for ZAO «Severnaya Zvezda» taking into account the proposed classification

### 5.2.1 First Level Product

Product portfolio is divided into three levels. First level product is considered to be a business direction or a group of goods. The product portfolio is allocated 6 first-level products, united by a common feature - the therapeutic effect. (See Figure 14)

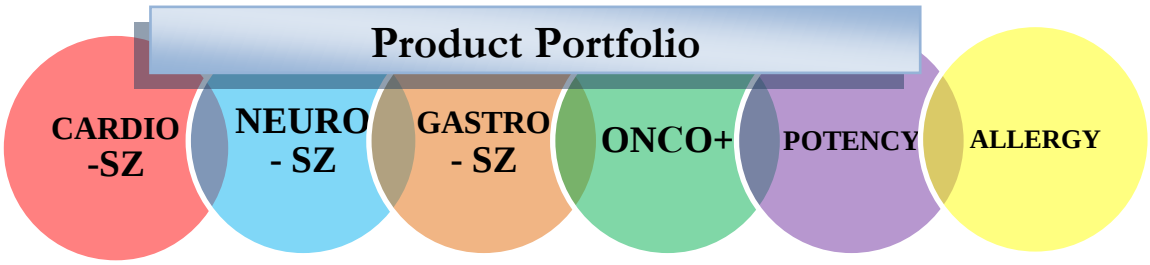


Figure 14. The first level products of the product portfolio of ZAO «Severnaya Zvezda»

Analysis conducted nosological (therapeutic) groups with the groups of goods in which the company operates. The data were obtained by analyzing the sales structure by ATC groups of products. From the overall analysis of the pharmacological market data estimate the market volume by nosology:

- Drugs used for treatment of cardiovascular diseases - Cardio - SZ (See Table 9);
- Drugs used for treatment of neurological diseases - Neuro - SZ (See Table 10);
- Drugs used for treatment of gastrointestinal diseases - Gastro - SZ (See Table 11);
- Drugs acting on the cellular level - "ONCO+" (See Table 12);
- Drugs used for sexual vigor improvement - Potency (See Table 13);
- Drugs used for treatment of allergy -Allergy (See Table 14).

Table 9. Medications used to treat diseases of the cardiovascular system (Cardio)

| **Segment of market:** | **Value volume mln rub..** | **Share, %** | **Actual volume, mln pack** | **Share, %** |
|---|---|---|---|---|
| Commercial segment | 64 721 | 12,6 | 455 | 10,8 |
| Reimbursement segment: | 2 521,6 | 3,0 | 20,6 | 30,0 |
| Hospital segment | 7 568,4 | 3,6 | 50,7 | 5,1 |

Table 10. Medications used to treat diseases of the nervous system (Neuro)

| Segment of market: | Value volume mln rub.. | Share, % | Actual volume, mln pack | Share, % |
|---|---|---|---|---|
| Commercial segment | 59 135 | 11,5 | 753 | 17,8 |
| Reimbursement segment: | 3 418,7 | 4,1 | 10,4 | 15,1 |
| Hospital segment | 18 654,6 | 8,9 | 96,4 | 9,7 |

Table 11. Medications used for the treatment of digestive tract diseases (Gastro)

| Segment of market: | Value volume mln rub.. | Share, % | Actual volume, mln pack | Share, % |
|---|---|---|---|---|
| Commercial segment | 99 856 | 19,5 | 737 | 17,4 |
| Reimbursement segment: | 13 041,5 | 15,5 | 17,5 | 25,5 |
| Hospital segment | 15 377,2 | 7,3 | 81,7 | 8,2 |

Table 12. Medications acting on a cellular level (Onko +)

| Segment of market: | Value volume mln rub.. | Share, % | Actual volume, mln pack | Share, % |
|---|---|---|---|---|
| Commercial segment | 19 438 | 3,2 | 122 | 2,9 |
| Reimbursement segment: | 40 828,3 | 48,4 | 3,1 | 4,4 |
| Hospital segment | 18 654,6 | 8,9 | 96,4 | 9,7 |

Table 13. Medications used to increase potency (Potency)

| Segment of market: | Value volume mln rub.. | Share, % | Actual volume, mln pack | Share, % |
|---|---|---|---|---|
| Commercial segment | 37 447 | 7,3 | 82 | 2,0 |
| Reimbursement segment: | 1 996,2 | 2,4 | 0,8 | 1,1 |
| Hospital segment | 3 266,1 | 1,6 | 4,7 | 0,5 |

Table 14. Medications used to treat allergies ("Allergy")

| Segment of market: | Value volume mln rub.. | Share, % | Actual volume, mln pack | Share, % |
|---|---|---|---|---|
| Commercial segment | 65 625 | 12,8 | 622 | 14,7 |
| Reimbursement segment: | 5 072,0 | 6,0 | 4,9 | 7,1 |
| Hospital segment | 5 615,6 | 2,7 | 32,0 | 3,2 |

In 2014, the volume of the product "Cardio - SZ" was 7.23 million packs, which correspond to 1.77% of the market share of cardio products, and 283 million rubles, which corresponds to 0.65% of the Russian pharmaceutical market share. The share of commercial market was 78.1%, while in the state – owned market 21.9%, including in the reimbursement segment about 4% and in the hospital segment about 17%. (see Table 9)

For the analysis of the first level product is used growth-share matrix.

**Construction of the BCG matrix for the first level products.**

The model proposed to use the BCG matrix for analysis the first level product. The matrix allows analyzing the dynamics of market relations and factors. In order to develop the strategy of the enterprise as related to the first level product with the help of the BCG, it is necessary to calculate the current matrix indicators, build it, reveal strategically unattractive products and exclude them, and then build a new BCG matrix. Current indicators for building the matrix are set forth in Table 15. The BCG matrix is presented on Figure 15. Analysis of the matrix is shown in Table 16.

Table 15. Current indicators of the first level products for building growth-share matrix

| № | Product: | Market growth, % | Relative market share,% |
|---|---|---|---|
| 1 | «Cardio-SZ» | 15,6 | 0,98 |
| 2 | «Neuro-SZ» | 12,8 | 0,05 |
| 3 | «Gasto-SZ» | 11 | 0,63 |
| 4 | «Onko+» | 12 | 0,04 |
| 5 | «Potency» | 12 | 0,006 |
| 6 | «Allergy» | 0 | 0,02 |

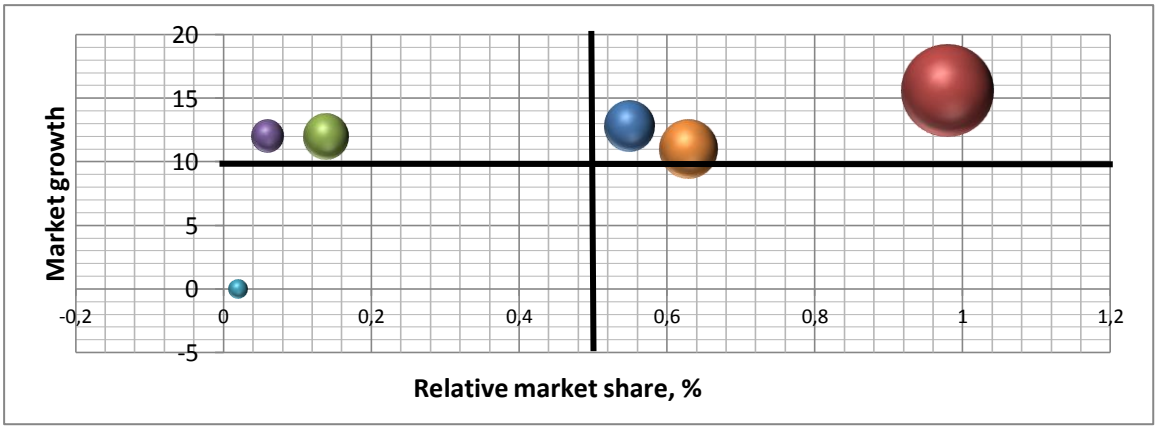


Figure 15. BCG matrix

Table 16. Analysis of the BCG matrix

| № | Product: | Market growth, % | Relative market share,% | Diameter: | BCGs quadrant |
|---|---|---|---|---|---|
| 1 | «Cardio-SZ» | 15,6 | 0,98 | 0,50 | Star |
| 2 | «Neuro-SZ» | 12,8 | 0,55 | 0,15 | Star |
| 3 | «Gasto-SZ» | 11 | 0,63 | 0,2 | Star - Cash Cow |
| 4 | «Onko+» | 12 | 0,04 | 0,12 | Question mark |
| 5 | «Potency» | 12 | 0,006 | 0,06 | Question mark |
| 6 | «Allergy» | 0 | 0,02 | 0,02 | Dog |

Out of the products manufactured by the enterprise, Gastro-SZ located at the intersection of "Stars" and "Cash Cows" quadrants. In order to save the volume sales of the product at the appropriate level the following actions are required: supporting advertising, flexible pricing policy, support with the existing distribution network, new modifications of the product. The gained profits may be used for support of other products and extension of the market share of this product. The priority objective becomes "Harvest". The Cardio-SZ is relates to "Stars" quadrant and brings high profit. It is recommended to reinvest most of these funds into the Cardio-SZ product to support and develop competitive advantages in conditions of growing competition. Neuro-SZ product is also refers to "Stars" quadrant. There may be the following strategy options for such products: gradual decreasing of the price, increasing of expenses for advertising, development and offer of new product modifications, etc. When development becomes slower - "star" will turns into a "cash cow". Product “ONCO+” and new product “Potency” are classified as "Wild Cats". Undoubtedly, they are prospective as they are launched at fast-growing markets but their promotion requires financial costs. In order to get competitive advantages, one needs a promotion program that takes into consideration peculiarities of competitors (pricing policy, advertising, marketing agreements, etc.). Product “Allergy” is a "Dog". The market of antiallergenic drugs is saturated with well-known competitors' products. On the market there are four generations of medications, so the consumer generally makes a choice based on their own experience in favor of the "old" and "known" drugs. “Allergy” product requires significant efforts for its promotion. Due to the fact that the product relates to a low price category and has no growth prospects, its further manufacturing is not justified. It is necessary to stop financing of the product and to expel it from the product portfolio. A new product portfolio is presented in Table 17. The new BCG matrix is shown on Figure 16.

Table 17. Performance of the new product portfolio

| № | Product: | Market growth, % | Relative market share,% | Diameter: | BCGs quad-rant |
|---|---|---|---|---|---|
| 1 | «Cardio-SZ» | 15,6 | 0,98 | 0,50 | Star |
| 2 | «Neuro-SZ» | 12,8 | 0,55 | 0,15 | Star |
| 3 | «Gasto-SZ» | 11 | 0,63 | 0,2 | Star - Cash Cow |
| 4 | «Onko+» | 12 | 0,04 | 0,12 | Question mark |
| 5 | «Potency» | 12 | 0,006 | 0,06 | Question mark |

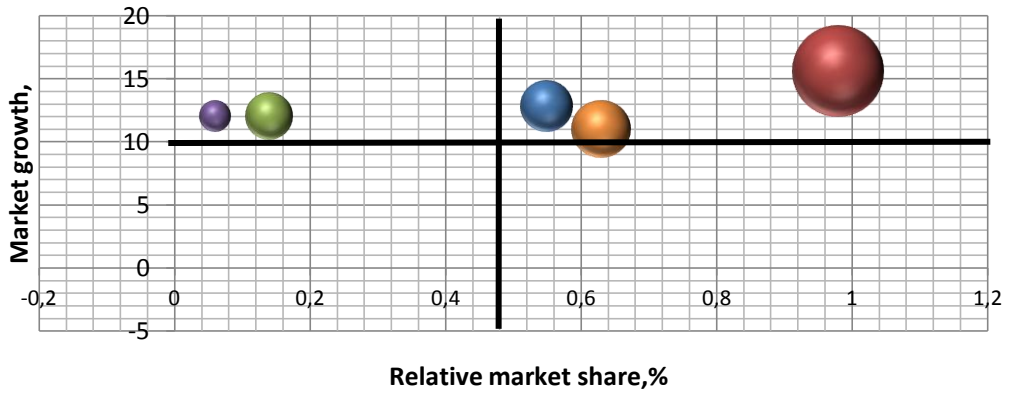


Figure 16. New BCG matrix

5.2.2 Second Level Product

Second level product is regarded as a trade line inside a group of goods. 18 second level products have been distinguished within the product portfolio ZAO ”Severnaya Zvezda” and they are united with the common feature - pharmacological action. It includes 7 products within the Cardio-SZ group, 4 products within the Neuro-SZ group, 4 products within the ONCO+ group, 1 product within the Gastro-SZ group, 1 product within the Potency group, 1 product within the Allergy group. There may be an unlimited quantity of second level products within first level products. In the portfolio such quantity is varied from one to seven.

According to Ministry of Health, the year 2015 dedicated to the fight against heart disease. The analysis with matrix method will be on the example of the group of drugs for treatment of cardiovascular system diseases. The first level product Cardio-SZ, drugs includes 7

directions regarding their pharmacological action. The diagram with consideration of the ATC classification can be schematically represented as follows (See Figure 17).

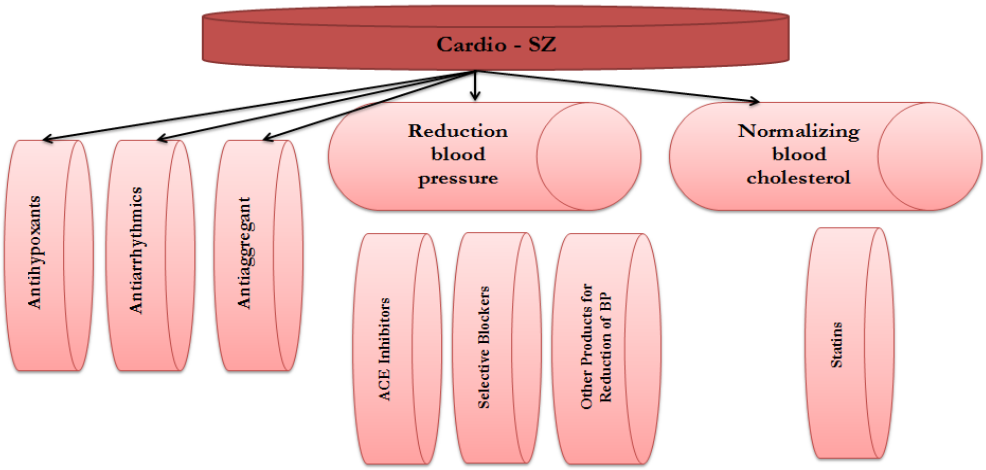


Figure 17. Diagram of the Cardio-SZ second level product

For the analysis of the second level product are used the ADL and Ansoff matrices.

**Analysis of Second Level Products on the example of the first level product Cardio-SZ**

Analysis of second level products was performed through market analysis and studies of dynamics. Changes in market shares of pharmacological groups took place due to increase of the number of patients,who suffer from various cardiovascular diseases, and by reasons of new drugs appearance (new active substances) and joint prescription of drugs from various pharmacological groups. For the second level products propose to use Ansoff and ADL matrices. The market analysis of the most significant diseases as well as analysis of the number of consumers (patients) was performed to make up the matrices. The data is presented in Table 18, on Figure 18 and Figure 19.

Table 18. Ratio of ATC groups in the volume of pharmacy sales of medicines in Russia in April 2014-2015,%

| **ATC - groups** | **Products of ZAO «Severnaya Zvezda»** | **The share of cost sales volume, rub.,%** | | | **The share of the actual volume sales pack.%** | | |
|---|---|---|---|---|---|---|---|
| | | **2014** | **2015** | **Shifts in market share,%** | **2014** | **2015** | **Shifts in market share, %** |
| **A**Alimentary tract and metabolism. | «Gasto-SZ» | 20,08 | 19,76 | -0,32% | 18,16 | 17,44 | -0,72 |
| **C** Cardiovascular system. | «Cardio-SZ» | 12,64 | 12,82 | 0,18% | 10,63 | 10,79 | 0,16% |
| **R** Respiratory system | «Allergy» | 11,62 | 11,28 | 0,49% | 13.49 | 14.85 | 1.36% |
| **N** Nervous system | «Neuro-SZ» | 11,62 | 11,28 | -0,34% | 18,37 | 16,96 | -1,42% |
| **G** Genito-urinary system and sex hormones | «Potency» | 7,37 | 7,17 | -0,20% | 1,82 | 1,95 | 0,13% |
| **B** Blood and blood forming organs | «Cardio-SZ» | 3,48 | 3,70 | 0,22% | 3,04 | 3,04 | 0,00% |
| **L** Antineoplastic and immunomodulating agents | «Onko+ | 3,69 | 3,59 | -0,09% | 1,73 | 1,53 | -0,20% |

The highest growth was demonstrated by the pharmacological groups used for treatment of alimentary tract and metabolism diseases. Pharmacological groups for treatment of cardio diseases took the II and VIII places on the rating list. The third place on the rating list took the pharmacological group for treatment nervous system. Let's review the pharmacological groups used for the treatment of cardiovascular diseases. Combined (joint) therapy is most often used for treatment of cardiology diseases, for example, Antihypoxants, Antiarrhythmics, ACE Inhibitors, Selective Blockers. Second level products are individually selected (prescribed) to each consumer (patient) by their physician.

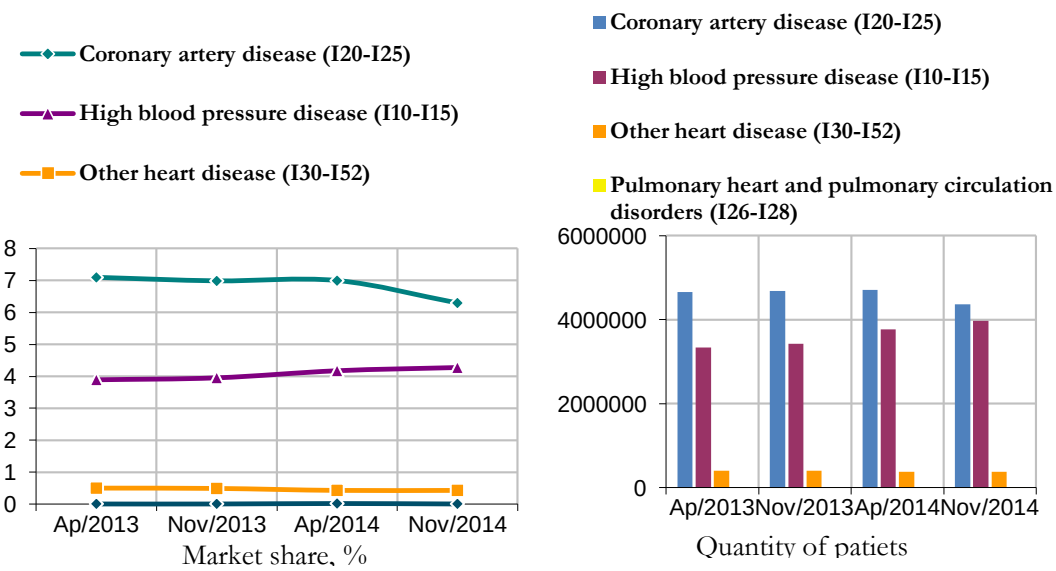


Figure 18. Dynamics of prescribing various pharmacological groups for the treatment of cardio diseases

Dynamics of prescription of products for treatment of blood pressure is set forth on Figure 19.

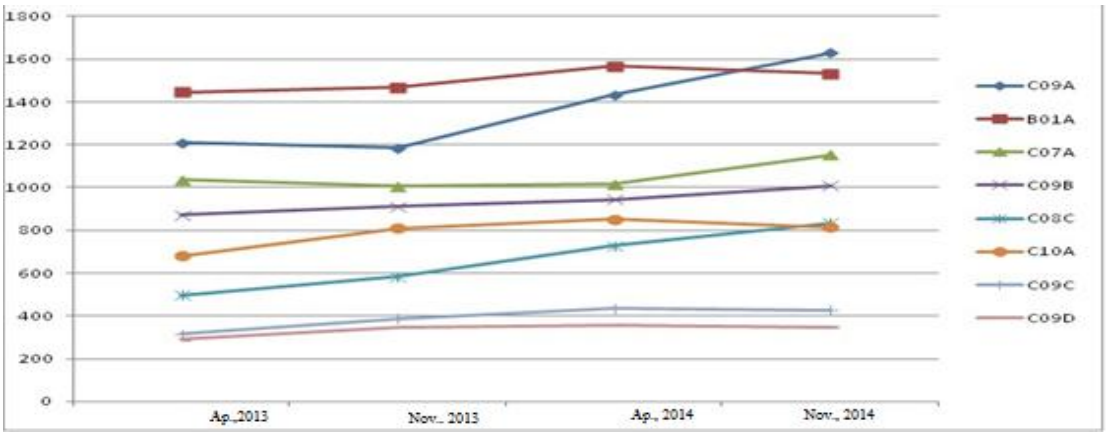


Figure 19. Dynamics of prescription of products for treatment of blood pressure

The dynamics of prescribing pharmacological groups (ATC)

- C09 – dynamics of the ACE Inhibitors product.
- C08 – dynamics of Other Products for Reduction of BP.
- C07 – dynamics of the Selective Blocker product.
- C10A – dynamics of the Antiarrhythmic product.
- C10A – dynamics of the Antiaggregant product.

**Development of the ADL matrix for second level products**

ADL matrix allows planning the strategy for second level products in accordance with the stage of life cycle of the Cardio-SZ group of goods (first level product) and the level of competitiveness are the market of cardiology drugs. The work with the matrix is performed in two stages. The position of the product within the ADL matrix is noted at the first stage: the stage of the life cycle of the product and its competitive position at the market is determined. The determination parameters of the stage of product development are following variables: growth rates, potential of the industry, the breadth of the product range, the number of competitors, the stability of market share, the standards of behaviour of customers, ease of entry, the level of technological development.

For instance, the width of the "Antihypoxants" product range in ZAO «Severnaya Zvezda» portfolios includes two generations of products regarding their pharmacological and technological properties:

- 20 mg film coated tables with usual release of the active substance (discontinued);
- 35 mg film coated tables with modified release of the active substance (still manufactured).

In the "Antihypoxants" product range 24 names are represented at the market including 12 brands, 5 umbrella brands, and 7 INNs. It includes 7 foreign manufacturers and 17 domestic manufacturers.

Define the following variables before proceeding to construct the matrix:

- the first variable of the matrix, which is the market maturity degree;
- the second variable of the matrix, which is the stability of positions of your company in the industry.

The method was applied to each second level product of the Cardio-SZ group **(**See Appendix 6). Various groups of experts (employees of the company, representatives of distributors, and representatives of pharmacy networks) were involved for a more objective assessment. Having analyzed the data of second level products, one can develop the matrix represented in Figure 20. The strategy is selected in accordance with placement of the product in the ADL matrix.

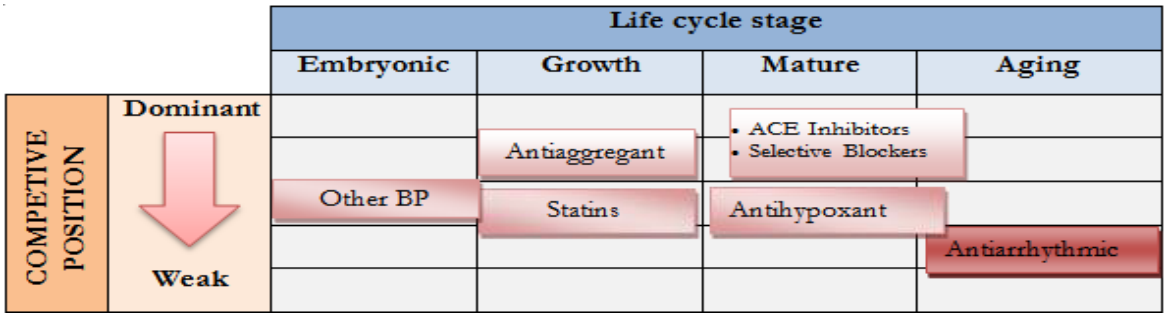


Figure 20. ADL matrix for the second level Cardio-SZ product

In accordance with matrix, the following strategies may be accepted for products.

The "selective attempt to improve position" strategy is recommended for the group of Other Drugs to Reduction of Blood Pressure (BP) for quick market share capturing. Sales growth objectives: equal to the market growth value and over it. Competitive advantages: to strengthen the current features. It requires selective investment.

The "attempt to improve position" strategy is recommended for the Antiaggregant group of products. Sales growth objectives: to keep the growth equal or a little bit over the market growth value. Competitive advantages: to keep the existing product qualities. Average level of investments: to keep only the investments that lead directly to market growth.

The "selective push for share" strategy is recommended for the group of Statins. Sales growth objectives: equal to the market growth value. Competitive advantages: to strengthen the current features of goods. It requires selective investment.

The strategy of keeping the niche and market share is recommended for products in groups of ACE Inhibitors and Selective Blockers. Sales growth objective is to keep the growth equal to the market growth value. Competitive advantages: to keep them on the existing level. Invest only in the case of decreasing of sales.

The "find niche and attempt to protect it" strategy is recommended for the Antihypoxant group of products. Sales growth objectives: equal to the market growth value. Competitive advantages keep at the current level. Cut down the investments to the minimum required level.

The "phased out withdrawal" strategy is recommended for the Antiarrhythmic group of products. No investments.

**Construction of the Ansoff matrix for the second level products.**

Matrix analysis was performed on example of drugs which normalize the level of cholesterol in blood (Statins with the Cardio-SZ group). Analysis of the rest of products was performed with the analogous method. The statins product is represented in the portfolio with INN Simvastatin. It is represented in the market as follows: 29 INNs including 16 brands, 6 umbrella brands, and 7 INNs. The products are represented by 22 foreign and 6 domestic manufacturers. Included into the VDL list in accordance with the data of 2014, the volume of sales comprises 1.03 bln rubles, which is less than 1% of the volume of sales of Vital and Essential Drugs in rubles. Commercial market comprises about 3.34 bln rubles. The growth of market comprises 7% in monetary terms and 10% in terms of number of packs. The Statins product has 6% in monetary terms and 10% in terms of number of packs within the product portfolio of the ZAO «Severnaya Zvezda» The product growth rate complies with the market growth rate. In accordance with the data of the first quarter of 2015, the growth tempo in monetary terms slowed down in connection with appearance of new competitors and decreasing of the price for packaging of products (See Appendix 7). On the basis of received data build the matrix (See Figure 21)

| | | PRODUCT | |
|---|---|---|---|
| | | Existing Products | New Products |
| MARKET | Existing Markets | Market Penetration | Statins |
| | New Markets | Market Development | Diversification |

Figure 21. I. Ansoff matrix for the second level product

Statins are in the Product Development quadrant. This strategy is possible for the enterprise, the risks are minimal, and as the company will be acting at a familiar market. It is recommended to take the following measures for its successful implementation:

- to concentrate on development and widening of the Statins product group: launch of new drugs and SKUs;
- search for new niches: geographical widening and program of joint prescription of products of various pharmacological and therapeutic groups (Ursodez® + Statins);
- extension of marketing agreements with wholesale and retail trading markets;

- stimulation of promotion (holding of training sessions with physician and pharmacists, participation in exhibitions, etc.).

### 5.2.3 Third Level Product

A third level product is the type of goods that satisfies the needs of a specific consumer or has the purpose of treatment of a specific symptom (symptoms) of a disease or ensuring the product range of the health care and prevention institutions and pharmacies for satisfying such needs. As a rule, all subjects of the pharmaceutics market are aware of the need for such product:

- management and regulation bodies, as a new product (drug) must be registered and pass all the required tests regarding efficiency and safety and approved for the use by end-consumer;
- manufacturers as they have developed and approved process regulations, production facilities, and manufacturing plan of production and sales of such product (ensures supply of such product at the market);
- distribution structure (distributors and pharmacy networks) as the product must be available in the quantity required to satisfy the demand;
- information resources as the information must be accessible to the consumer (in reference books, at exhibitions, on the Internet, etc.);
- physician as they prescribe (recommend) such product;
- consumers (patients) that use this product.

A third level product is the type of goods with similar technical and process features that may include various types of packaging, filling, and dosage. Several third level products comprise a second level product. Allocation of such products is represented in Table 19 for the Cardio-SZ first level product with consideration of classification.

Other products were classified similarly (See Appendix 8,9,10,11,12).

Table 19. Cardio-SZ products allocation

| I | CARDIO ( therapeutic effect) | | |

For analysis of the third level product review INN Simvastatin (See Figure 22). Simvastatin has been present at the Russian pharmaceutical market for 8 years. Over the previous 5 year, the trend of decreasing of the market share has been observed due to entering of new generation drugs to the market. Thus, during 2010 to 2014, the share of Simvastatin was decreased in the governmental segment from 56.4 percent to 29.0 percent, and from 43.0 percent to 14.8 percent in the commercial segment. (The newspaper "Pharmaceutical Bulletin", 2015)

The following trends are observed regarding the Simvastatin INN data in the portfolio of ZAO «Severnaya Zvezda»:

- the growth of sales comprised 6% in packs and 9% in rubles during the period of 2012 to 2013;
- the growth of sales comprised 1.2 % in packs and 2% in rubles during the period of 2013 to 2014.

The growth of sales was caused with the pricing policy and shaking weaker players out of the market.


Figure 22. Third level product INN Simvastatin of ZAO «Severnaya Zvezda» product portfolio

Analyze Simvastatin INN product with the BCG matrix algorithm for the 1 half-year of 2015 is represented on Table 20 and Figure 23.

Table 20. Current figures for INNs "Simvastatin"

| Product | Volume Value, thousand rub | | Market growth, % | Market share, % | | Relative market share, % | Diameter | BCG quadrant |
|---|---|---|---|---|---|---|---|---|
| | 2014 | 2013 | | Severnaya Zvezda | Zodak * | | | |
| INN Simvastatin | 60978 | 52098 | 1,2 | 6 | 17 | 0,35 | 0,06 | Cash cow |

* The leading competing product in the current market

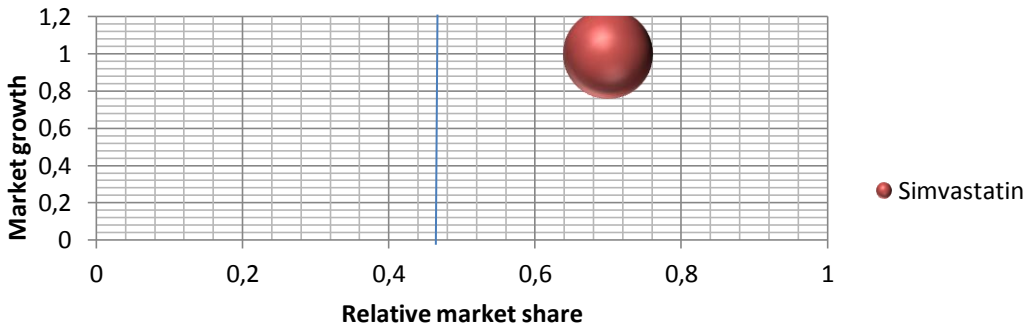


Figure 23. BCG Matrix of product "INN Simvastatin"

The product INN Simvastatin is refers into the "Cash Cow" quadrant. In order to keep the product sales volumes on the right level required: supporting advertising, flexible pricing policy, geographical extension of the sales network, new modifications of the product. The gained profits may be reinvested into the product, into other current products, into new products, and into the search for new niches. The priority objective becomes "Harvest".

In 2012, the company performed market analysis and revealed the trend of decreasing of the Simvastatin share at the market of Statins. For selection of the objective product support strategy analyze the market of Statins. The Statins group includes the following active substances: Atorvastatin, Lovastatin, Pravastatin, Rosuvastatin, Simvastatin, etc. Atorvastatin, Rosuvastatin, and Simvastatin hold a significant share at the Russian pharmaceutical market.

Simvastatin is represented at the market as follows: 29 INNs including 16 brands, 6 umbrella brands, and 7 INNs. The products are represented by 22 foreign manufacturer and 6 domestic manufacturers (State Register of medicines, 2015). Included into the list of Vital and Essential Drugs in accordance with the data of 2012, the volume of sales comprises 1.03

billion rubles, which is less than 1 percent of the volume of sales of Vital and Essential Drugs in rubles. Commercial market volume of Simvastatin comprises about 3.34 billion rubles.

Atorvastatin is represented at the market as follows: 25 INNs including 17 brands, 4 umbrella brands, and 4 INNs. The products are represented by 17 foreign manufacturer and 8 domestic manufacturers (State Register of medicines, 2015). Included into the list of Vital and Essential Drugs in accordance with the data of 2012, the volume of sales comprises 2 billion rubles, which is 1.55 percent of the volume of sales of Vital and Essential Drugs in rubles. Commercial market volume of Atorvastatin comprises about 10.77 billion rubles

Rosuvastatin is represented at the market as follows: 11 INNs including 9 brands and 2 umbrella brands. The products are represented by 7 foreign manufacturer and 4 domestic manufacturers (State Register of medicines, 2015). Not included into the list of Vital and Essential Drugs. According to the data of 2012, the volume of sales at the commercial market comprised 20 billion rubles; according to the data of 2013, the volume of sales at the commercial market comprised 24 billion rubles.

The market of Statins of 2007: Simvastatin: about 52 %; Atorvastatin: about 29%; Rosuvastatin: about 4 %; other Statins: about 15% (See Figure 24). Other Statins were not reviewed in the analysis.

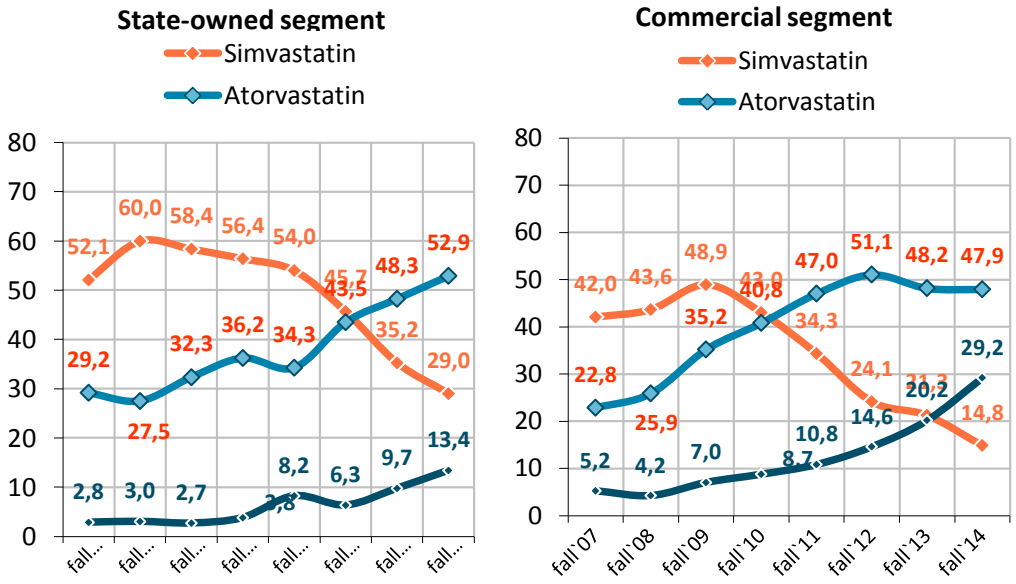


Figure 25. Shares of medications of the Statins pharmacological group, (DSM Group)

Changes of the share of drugs of the Statins pharmacological group for the period of 2013 to 2014 by market segments:

- share of Simvastatin dropped in the commercial segment from 21,3% to 14,8 %, and in the governmental procurements segment it dropped from 32,5% to 29%;
- share of Atorvastatin has remained quite high for the previous 3 years (about 40%) and continues to demonstrate regular growth in the both market segments. In the segment of government procurements, its share grew from 48,3% to 52,%. The commercial segment demonstrated insignificant drop of share from 48,2% to 47,9%. Changing of the share in the commercial segment is caused with the fact that many foreign and domestic manufacturers have entered the market. The market share in packs has not changed.
- share of Rosuvastatin rose in the commercial segment from 20,2 % to 29,2%, and in the governmental procurements segment it rose from 9,7% to 13,4%.

Based on the performed analysis, it is recommended to reinvest the profits from Simvastatin INN into the following programs. Support "INN Simvastatin": perform rebranding into an umbrella brand to keep the market share. Invest part of profits into development, registration, and market launch of a new product with new active ingredient "Atorvastatin", the market of which is mature, with a developed competitive structure. Market growth in the segment of governmental procurements is observed. The strategy of quick market launch, promotion, cooperation with physicians and pharmacists, use of the umbrella brand is required. As there are domestic manufacturers at the market, immediately after market launch the product may take the share of about 1% in the commercial segment and about 5% in the governmental segment. Invest part of profits into development, registration, and market launch of a new product with new active ingredient "Rosuvastatin". The market is at the stage of growth with not yet formed competitive environment. The strategy of quick market launch, promotion, active use of marketing agreements with pharmacy networks, use of the umbrella brand is required. There is only one domestic manufacturer at the market, so immediately after market launch the product may take the share of about 4% in the commercial segment and about 10% in the reimbursement segment.

### Development of the ADL Matrix for Third Level Products

ADL matrix allows planning the strategy for both second and third level products in accordance with the stage of life cycle of the Cardio-SZ segment (first level product) and the level of competitiveness are the market of cardiology drugs. The tables similar to the tables for second level products were used for the analysis. For a more objective assessment of the strategy accepted for portfolio management, the matrix of third level products may be imposed onto the matrix of second level products. Such methodology may be applied for analysis of products at the same market segment (e.g. Cardio-SZ). The joint matrix is presented on Figure 26.

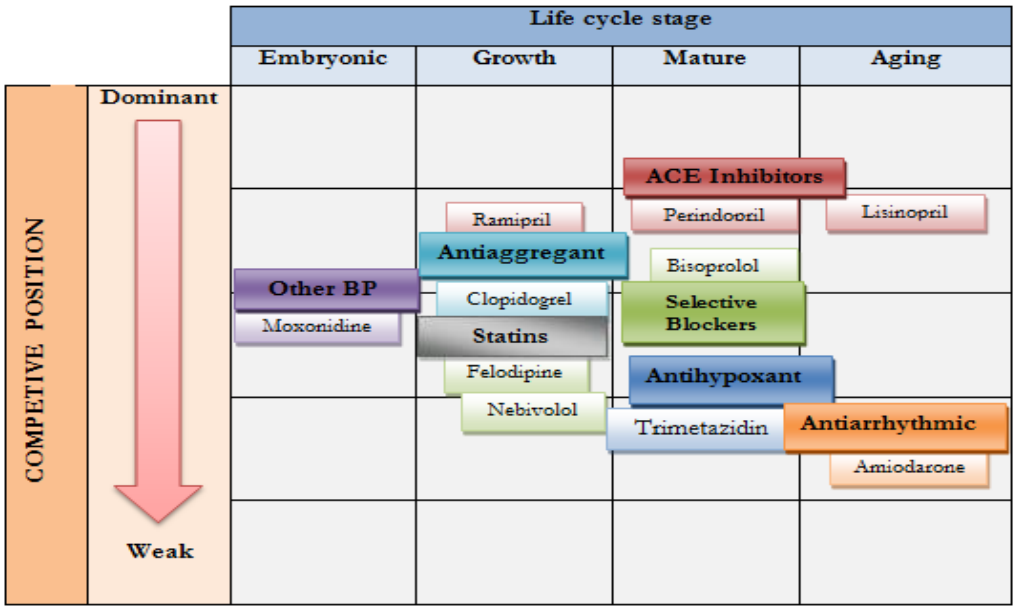


Figure 26. ADL Matrix of the Cardio-SZ third level products

In accordance with ADL matrix, the following strategies may be accepted for third level products.

The "selective attempt to improve position" strategy is recommended for the Moxonidine product. One should wait for the favorable situation for quick capturing of the market share. Sales growth objectives: equal to the market growth value and over it. Competitive advantages: to strengthen the current features of goods or services. Selective investments are to be made only into the projects capable of significant improvement of the company in the industry.

The strategy of holding positions is recommended for the Clopidogrel and Ramipril products. Sales growth objectives: to keep the growth equal or a little bit over the market growth value. Competitive advantages: to keep the existing product qualities. Average level of investments: to keep only the investments that lead directly to market growth.

The "selective push for share" strategy is recommended for the Simvastatin and Felodipin products. One should wait for the favorable situation for quick capturing of the market share. Sales growth objectives: equal to the market growth value. Competitive advantages: to strengthen the current features of goods or services. Selective investments only into the capable projects for significant improvement of the company in the industry.

The "find niche and protect it" strategy is recommended for the Nebivolol product. Sales growth objectives: equal to the market growth value. Competitive advantages: to strengthen the current features of goods or services. Selective investments only into the capable projects for significant improvement for the company in the industry. One must be careful with investments - the risk of low return on investment is increased.

The strategy of holding positions and keeping the market share in the segment is recommended for the Perindopril and Bisoprolol products. Sales growth objectives: to keep the growth equal to the market growth value. Competitive advantages: to keep them on the existing level. Only invest in the case of decreasing of sales.

The "find niche and hang on" strategy is recommended for the Trimetazidin product. Sales growth objectives: equal to the market growth value. Keep the competitive advantages on the existing level. Cut down the investments to the minimum

The holding positions strategy is recommended for the Lisinopril product. Sales growth objectives: to withstand dropping for the maximally long time. Cut down expenses for maximization of profits. If possible, refrain from reinvestments.

The "phased out withdrawal" strategy is recommended for the Amiodaron product. No investments and p reparation to leaving the market.

### Additional Analytical Study of the Potency Product

A prospective direction of market development is potency regulation drugs, which were revealed in the course of analysis of the market in 2010 to 2014. A representative of this segment is Viagra brand, INN Sildenafil. The expiration date of patent protection in May 2014. Data provided by the company. The company took the solution to develop the INN Sildenafil drug, register it, and launch it to the market. As launching of the product to market takes four years, additional studies are necessary for determination future position of the product and promotion strategy. In 2014 Sildenafil was represented in the Russian Federation with three drugs (See Table 21).

Table 21. INNs market: Sildenafil in Russia, 2014

| Product | Manufacturer | Dosage | SKU | Price per pack. rub. (4 tablets) |
|---|---|---|---|---|
| Viagra | Pfizer, Germany | 100mg | 5 | 2663 – 2745 |
| | | 50mg | | 2275 – 2325 |
| | | 25mg | | 996 – 1091 |
| Sildenafil | Pliva, Croatia | 100mg | 4 | 778 – 792 |
| | | 50mg | | 505 – 585 |
| Dinamika | Teva, Israel | 100mg | 4 | 654 – 710 |
| | | 50mg | | 497 – 553 |

According to State Register of medicibes, all foreign manufacturers have brands to make promotion of the drug easier, and it is proposed to use the INN to cut down the costs. The following dosage is recommended for manufacturing: 25 mg, 50, mg, 100 mg. Availability of SKU with the dosage of 25 mg will guarantee big market share to our product and make it competitive with the main competitive (Viagra). Price is one of the competitive advantages of the drug manufactured by ZAO «Severnaya Zvezda».

Were developed the general recommendations regarding third level products. Technological and qualitative changes of the current products at the current market must be developed for the purpose of getting new consumer properties (FORTE drugs (increasing of dosage), drugs with modified release of active ingredient, drugs with prolonged release, etc.). Analysis must be performed and measures must be developed for entering new markets (geographical extension). In connection with the fact that patients (consumers) usually have several diseases or symptoms, studies must be performed and joint prescription of third level products of various pharmacological and therapeutic groups must be recommended

(gastro+cardio, cardio+cardio); corresponding strategy of joint promotion must be developed. The number of SKUs must be optimized for the purpose to cut down the costs (bigger packs for hospital segment). Investments must be made into promotion and creation of a new information image. Individual approach to pricing strategy must be developed for each product with consideration of its competitive environment and planned volume of investments.

ABC, ZYX, ABC+ZYX methods of product range analysis may be applied for development of analysis inside INNs.

In the thesis were determined strategies for 2016 to 2018, described measures required for their implementation, and determined financial costs The assessment of economic efficiency of implementation of the product portfolio management model can be found in the Appendix 13.

## 5.3 The results of the economic evaluation of the introduction of a new product portfolio management model for the enterprise ZAO «Severnaya Zvezda».

The project reviewed regarding improvement of the product portfolio of active enterprise for manufacturing of drugs, ZAO «Severnaya Zvezda» efficient.

The project will allow extension and optimization of the product range and will bring the net profit of 44 million 174 thousand rubles during 4 years of its implementation. The rate of return from investment will comprise 2 (i.e., every 2 rubles invested into production facilities will bring 2 rubles of net profits from sales of ready products). The payback period of the project is 2 years and 3 months, which is less than the period of implementation of the project itself (i.e., the project will be paid back in half of the term of its implementation).The received indicators allow making the conclusion that the project is efficient and must be introduced at the enterprise.

# 6 RECOMENDATIONS & CONCLUSION

In this thesis has been studied theoretical aspects of formation and management of the product portfolio with consideration of rapid changes of the environment. Based on research was improved portfolio management model for the pharmaceutical company, which takes into account the nuances and limitations of the industry. They include economic sanctions and strict state regulation of production and prices.

The main goal of the thesis was to develop new algorithm of the product portfolio management. As a result were developed specific practical recommendations for pharmaceutical companies. The proposed model was experimentally verified on the basis of close joint stock pharmaceutical enterprise ZAO «Severnaya Zvezda».

The developed provisions may be considered as a methodological basis for taking management solutions at various management levels. The system of main components of the product portfolio has been developed in the case study, which may be used for assessment of efficiency of the current portfolio, as well as for determination of development of the product portfolio. The model allows making the optimum plan of manufacturing and promotion of products in accordance with consumers' requests and cutting down expenses of the enterprise. Depending on the role of products in portfolio, they were grouped and classified in accordance with their characteristics. The use of matrices provides visual presentation of the "contribution" of individual products to the overall financial result for a certain period. The model allows simplifying multi-component portfolios by exclusion of many secondary factors from reviewing, which makes portfolio assessment simpler and more understandable.

The following strategies have been proposed for ZAO «Severnaya Zvezda» portfolio management based on the forecast of the market:

- development of first level products with consideration of development of market segments and selection of new prospective directions;
- development of new generations products;
- perfection of technological and qualitative characteristics of current products at current markets for the purpose of getting new consumer properties;

- entering to new markets (geographical extension);
- joint promotion of various products (gastro+cardio);
- price strategy for each product with consideration of its competitive environment and planned volume of investments.

These recommendations for product portfolio management take into account and used on enterprise ZAO «Severnaya Zvezda». (See Appendix 14).

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Sales statistics of ZAO «Severnaya Zvezda» for 2012 - 2014.

Analytical study of the product group “Statins”, conducted in 2012.

Analysis of the prospective directions of Russian pharmaceutical market development for 2010 - 2014.

LIST OF APPENDICES

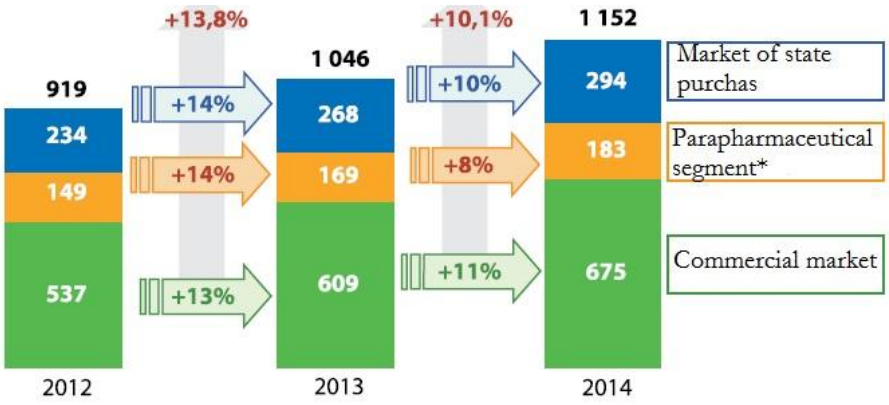
Appendix 1. The current situation on the Russian market.

According to DSM Group, at the end of 2014, the volume of Russian pharmaceutical market amounted to 1152 billion rubles in the prices of final consumption, which is 10% more than in 2013. Comparison of market volume is presented in Table 1.

Table 1. Comparison of volume of the Russia pharmaceutical market 2013 - 2014

| **Market** | **Market size in terms of value (cost) 2013, bln rub** | **Market size in terms of natural product 2013, bln pack.** | **Market size in terms of value (cost) 2014, bln rub** | **Growth, %** | **Market size in terms of natural product 2014, bln pack.** | **Growth, %** |
|---|---|---|---|---|---|---|
| Commercial market | 609 | 4,4 | 975 | 11% | 4,2 | -4.5% |
| State market | 267 | | 294,2 | 10,2% | | |
| Hospital segment | 84,4 | | 84,4 | | | |
| Reimbursement segment | 182,6 | | 209,8 | 15% | | |
| TOTAL | 1 045 | | 1 152 | | | |

The capacity of the commercial market in 2014 amounted to 975 billion rubles in the prices to final consumption, or 513 billion rubles in pharmacy purchase price (See Table) which is 11% more than in 2013. It was realized 4.2 billion packages, which is 4.5% less than in 2013. The share of the State-owned segment (Hospital + Reimbursement) was about 25.5%. As a result, ¾ of the pharmaceutical market is realized at the expense of own funds of the population. The graphs of Figure 1 show the dynamics of the volume of the Russian pharmaceutical market in 2012-2014 in retail prices.




**Para pharmaceutical segment is not included in the case study*

Figure 1. Capacity of the Russian pharmaceutical market, bln rubs.

In 2014, the commercial segment of medications is growing at a rate comparable to the growth of the market as a whole and with the state segment. Government policy in public drug supply of the population remains the same, and articles that bear a social character, does not decrease. Over 2014 growth in ruble terms Hospital and Reimbursement segments accounted for 10% (DSM Group, 2015).

The main driver of market growth is inflation. It is comparable to the State Statistics Committee index of consumer prices, and on the basis of 2014 price increases for drugs amounted to approximately 12.7% (which is significantly higher than in previous years). Packages commercial segment of medicines shows a negative trend. Such dynamics is caused by a decrease in sales of products in the price range up to 50 rubles (50% loss in market volume fall on this segment). However, this factor has several reasons: on the one hand, consumers are placing more demands on the quality of medicines and prefer a more expensive drug. On the other hand, inflation in this segment is the highest - almost 28%. This leads to the fact that consumers are not buying the "traditional" cheap drugs for the future, which is also a reason for the change of the market structure (DSM Group, 2015).

New medicines are launched to the market every year. According to the State Registry of Pharmaceutical Drugs more than 28000 of medicinal product have been registered in the territory of Russia. The market is saturated not mainly by new original substances (innovators), but by already familiar substances (generics). Substances, having the same Active Pharmaceutical Ingredient API are often hidden by different trade names. Actually,

this is the same substance. For example, there are 32 synonyms of aspirin, more than 20 of Analgine, 38 of Paracetamol (State Register of medicines, 2015).

More than half of the registered drugs on the market make up the "top group", which consist of five-six pharmaceutical groups drugs out of 30 according to the International Classification of Diseases. These medicines are for the treatment of infectious diseases, cardiovascular, gastrointestinal diseases, analgesics, antipyretics, nonsteroidal anti-inflammatories, hormonal agents. However, an insufficient number of individual pharmacological groups of drugs are registered for treatment of rare or social diseases.

COMMERCIAL SEGMENT

In value terms, the share of domestic drugs is about ¼ of the Russian commercial market of medicines and in 2014 amounted to 24.3%. At the same time domestic drugs prevail in retail sales in volume terms - 55.3%. Note that in 2014 the share of domestic drugs in packages has decreased by almost 2%. The increase in sales of imported drugs was equivalent to the increase in domestic sales volume of drugs in value: + 11% by foreign drugs and 10% by Russian agents. In natural terms, sales of Russian drugs decreased by 7.6%, while for imported products reduction amounted about 0.5%. The structure of the commercial market in terms of sales of domestic and imported products is reflected in Figure 2.

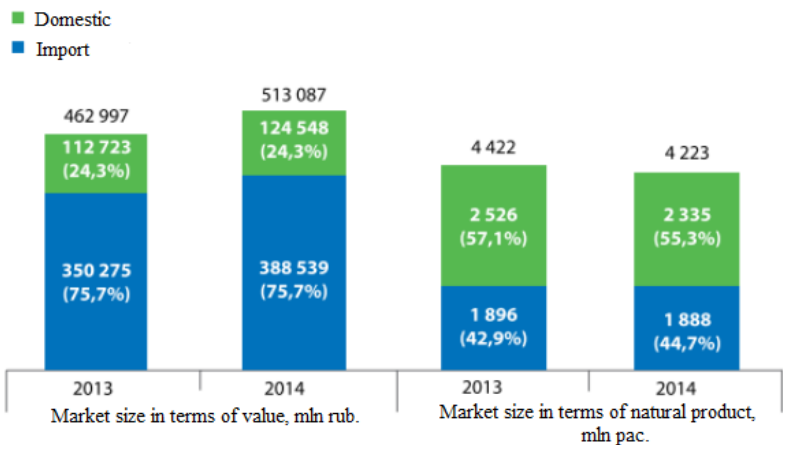



Figure 2. The sales ratio of imported and domestic drugs of commercial market in pharmacies prices, 2014 (DSM Group, 2015)

At the end of 2014 the commercial market of drugs in value terms increased sales of both prescription and non-prescription drugs. Typically, sales of Rx drugs are growing at a higher

rate than sales of OTC drugs. According to DSM Group data, sales of Rx-drugs grew in rubles by 12.7%, while OTC drugs sales growth was 8.9%. In natural terms also recorded similar dynamics; "-6.0%" - an increase in sales of OTC drugs, and "1%" – growth of RX-drugs. The share of Rx drugs in rubles amounted to 50.1%; in natural terms is dominated by OTC drugs (69.6%). Note that the average value of Rx-drugs was 200 rubles, while the price of OTC-drugs, on average, 2.5 times less - 87 rubles per pack. The ratio of the volume of pharmacy sales of Rx and OTC drugs is shown in Figure 3.

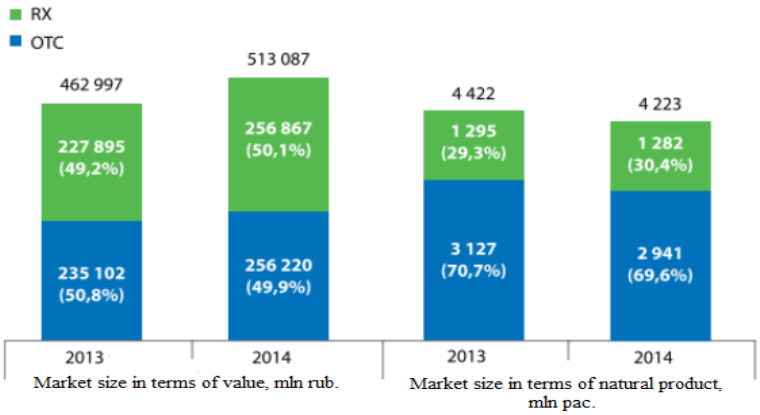



Figure 3. The sales ratio of OTC and Rx drugs of retail commercial market in Russia, 2014, (DSM Group, 2015)

The structure of the commercial market by ATC-groups each year is relatively stable. Value of pharmacy sales by first level of ATC groups in Russia is presented in the Table 2.

Table 2. Structure of sales of Russian Commercial market by ATC-groups, 2014

| **ATC groups of I level** | | **Market size in terms of value (cost), mln rub.** | **Share of the group in market size, %** | **Market size in terms of natural product, mln pack.** | **Share of the group in market size, %** |
|---|---|---|---|---|---|
| **Code** | **Contents** | | | | |
| A | Alimentary tract and metabolism | 99 856 | 19,5% | 737 | 17,4% |
| R | Respiratory system | 65 625 | 12,8% | 622 | 14,7% |
| C | Cardiovascular system | 64 721 | 12,6% | 455 | 10,8 |
| N | Nervous system | 59 135 | 11,5% | 753 | 17,8% |
| J | Antiinfectives for systemic use | 40 911 | 8,0% | 290 | 6,9% |
| M | Musculo-skeletal system | 40 350 | 7,9% | 281 | 6,7% |
| G | Genito-urinary system and sex hormones | 37 447 | 7,3% | 82 | 2,0% |

| ATC groups of I level | | Market size in terms of value (cost), mln rub. | Share of the group in market size, % | Market size in terms of natural product, mln pack. | Share of the group in market size, % |
|---|---|---|---|---|---|
| **Code** | **Contents** | | | | |
| D | Dermatologicals | 31 825 | 6,2% | 445 | 10,6% |
| L | Antineoplastic and immunomodulating agents | 19 438 | 3,2% | 122 | 2,9% |
| B | Blood and blood forming organs | 17 430 | 3,4% | 60 | 1,4% |
| ~ | Medicaments, without ATC-group | 16 053 | 3,1% | 210 | 5,0% |
| S | Sensory organs | 13 383 | 2,6% | 103 | 2,4% |
| H | Systemic hormonal preparations, excluding sex hormones and insulins | 2 902 | 0,6% | 25 | 0,6% |
| V | Various | 2 520 | 0,5% | 18 | 0,4% |
| P | Antiparasitic products, insecticides and repellents | 1 491 | 0,3% | 19 | 0,5% |

In 2014 the leading position, as in previous years, retained products of ATC - group [A] «Alimentary tract and metabolism» (19,5%), [R] «Respiratory system» (12,8%), [C] Cardiovascular system (12,6%), [N] Nervous system (11,5%) and [J] Antiinfectives for systemic use (8%). TOP-3 groups of drugs amounted about 50% of the market growth as a whole (DSM Group, 2015). State-owned segment

STATE SEGMENT: Hospital Subsegment

According to the dynamics of hospital purchases by quarters, in second half of the year purchases increased. (See Figure 4) In 2014, total costs reached 209,8 bln rub., which is 14,8% more than in 2013.

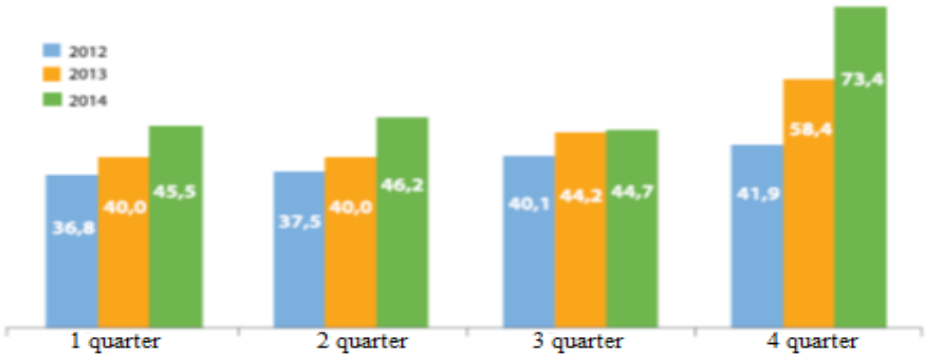



Figure 4. Dynamics of hospital purchases by quarters

An increase of purchases in Q4 2014 is explained by high growth of rates. Purchases of hospitals relatively the Q4 2013 increased by 26% in value terms and 13% in term of natural product. Thus, the hospital made a medicines stock for 1st quarter of 2015. (See Figure 5)

The volume of purchases of imported drugs in 2014 has grown in rubles 12% of domestic products increased by 23%. In natural product terms, the volume of imported drugs purchases dropped by 1%, while domestic - increased by 6%. As in the previous year, the segment in value terms is dominated by imported products, while the volume of packages in the lead domestic drugs. The cost of one pack of imported medicines almost 8 times higher than the cost of one package purchased from domestic producers. In 2014, one imported packaging an average cost 575 rbl and domestic only 72 rbl. According to the current dollar exchange rate 1 dollar = 60 rubles it is approximately 9.5 dlr and 1,2 dlr. Thus domestic products occupy about 25% of the volume in terms of value and 73% in terms of natural product (DSM Group, 2015).

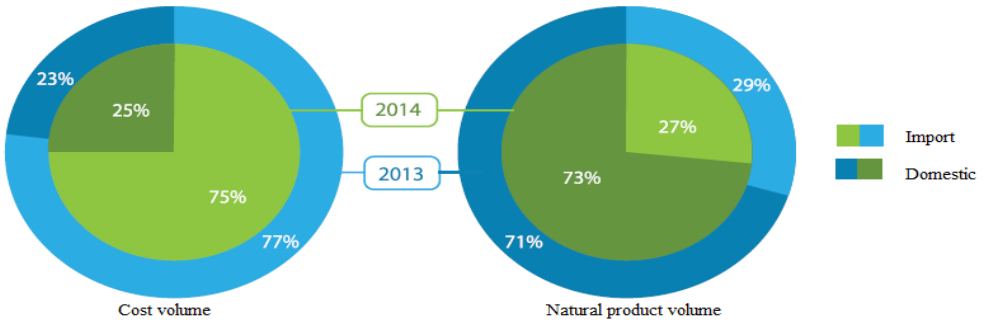



Figure5. The sales ratio of imported and domestic medicines in Hospital segment

Rating of medicines of Hospital segment by ATC groups is significantly different from the commercial market. Rating ATC groups in comparison with 2013 has not changed. The sales structure of the segment by ATC-groups is presented in the Table 3.

Table 3. The sales structure of the Hospital segment by ATC-groups, 2014

| ATC groups of I level | | Market size in terms of value (cost), mln rub. | Share of the group in market size, % | Market size in terms of natural product, mln pack. | Share of the group in market size, % |
|---|---|---|---|---|---|
| **Code** | **Contents** | | | | |
| J | Antiinfectives for systemic use | 73 902,3 | 35,2% | 289,3 | 29,0% |
| B | Blood and blood forming organs | 34 362,9 | 16,4% | 325,6 | 32,6% |
| L | Antineoplastic and immunomodulating agents | 29 941 | 8,9% | 96,4 | 9,7% |
| N | Nervous system | 18 654,6 | 8,9% | 96,4 | 9,7% |
| A | Alimentary tract and metabolism | 15 377,2 | 7,3% | 81,7 | 8,2% |
| V | Various | 9 013,8 | 4,3% | 11,6 | 1,2% |
| C | Cardiovascular system | 7 568,4 | 3,6% | 50,7 | 5,1% |
| R | Respiratory system | 5 615,6 | 2,7% | 32,0 | 3,2% |
| M | Musculo-skeletal system | 4 741,9 | 2,3% | 21,9 | 2,2% |
| G | Genito-urinary system and sex hormones | 3 266,1 | 1,6% | 4,7 | 0,5% |
| H | Systemic hormonal preparations, excluding sex hormones and insulins | 2 454,8 | 1,2% | 14,5 | 1,5% |
| S | Sensory organs | 2 025,4 | 1,0% | 6,6 | 0,7% |
| D | Dermatologicals | 1 860,2 | 0,9% | 50 | 5,0% |
| ~ | Medicaments, without ATC-group | 976,5 | 0,5% | 2 | 0,2% |
| P | Antiparasitic products, insecticides and repellents | 47,2 | 0,0% | 0,4 | 0,0% |

The leading groups of drugs according to the ATC classification in the hospital segment by the end of 2014:

- [J] Antiinfectives for systemic use;
- [B] Blood and blood forming organs;
- [L] Antineoplastic and immunomodulating agents;
- [N] Nervous system;
- [A] Alimentary tract and metabolism;

STATE SEGMENT: Reimbursement subsegment

Additional medicinal provision of certain categories of citizens is one of the measures of social support for population. The Reimbursement program mostly "imported", the domestic production takes small place in amount of drugs. The main task of the government according to the program "Pharma 2020" is to cardinally reverse this situation: the result is to increase the share of domestic products to 50%. Therefore, in the market, and in

particular the program providing preferential drugs there is a tendency to the appearance of an increasing number of home agents that are able to replace imported analogs.

At the end of 2014 the share of domestic products in terms of value decreased by 1% (See Figure 6). The increase in costs for the domestic medicines purchases decreased by 9.2% while consumption of imported products increased by 0.9%. The ratio is maintained for the benefit of imported drugs: 87% of the value of imported products account for the origin and 13% for domestic drugs. In natural product terms, the share of domestic medications for the first few years has increased (+ 2%). However while maintaining a downward trend in packages sales of both domestic and imported drugs: in 2014 the sales of domestic products fell by 4%, imports by 12%.

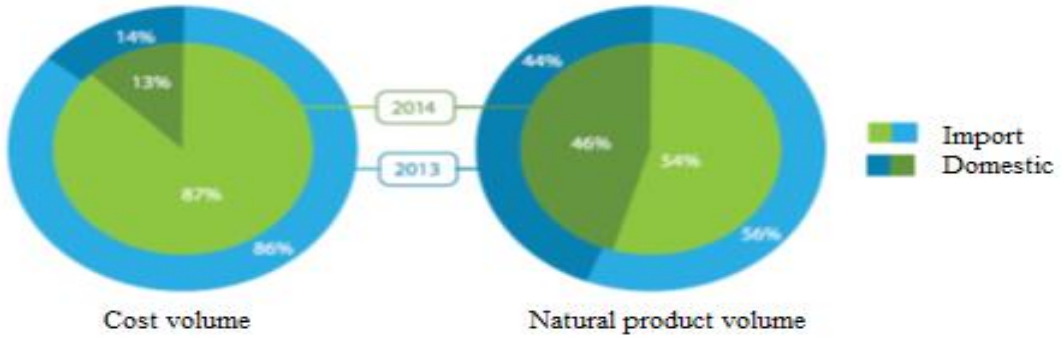



Figure 6. The sales ratio of imported and domestic medicines in Reimbursement segment

According to report of DSM Group, in the first three months of 2015 were purchased 25.8 million packages of drugs in the amount of 48.7 billion rubles. Compared with the first three months of last year the volume of purchases in packages unchanged (+ 0.02%), and in rubles increased by 25.1%. In 2015, the decline in volume of purchases in packages of medicines domestic production is 10.7%. Imported medicines were purchased on 9.9% more. About 50% in the value of the purchase is necessary, as in the last year, antineoplastic and immunomodulation agents' medications.

The structure of the top five by ATC groups in 2014 has not changed compared to the year 2013: the share in value volume was about 89%. The structure of the reimbursement segment by ATC-groups in Russia is presented in the Table 4.

Table 4. The sales structure of Russian Reimbursement segment by ATC-groups, 2014

| ATC groups of I level | | Market size in terms of value (cost), mln rub. | Share of the group in market size, % | Market size in terms of natural product, mln pack. | Share of the group in market size, % |
|---|---|---|---|---|---|
| **Code** | **Contents** | | | | |
| L | Antineoplastic and immunomodulating agents | 40 828,3 | 48,4% | 3,1 | 4,4% |
| A | Alimentary tract and metabolism | 13 041,5 | 15,5% | 17,5 | 25,5% |
| B | Blood and blood forming organs | 12 213,8 | 14,5% | 5,1 | 7,4% |
| R | Respiratory system | 5 072,0 | 6,0% | 4,9 | 7,1% |
| N | Nervous system | 3 418,7 | 4,1% | 10,4 | 15,1% |
| C | Cardiovascular system | 2 521,6 | 3,0% | 20,6 | 30,0% |
| H | Systemic hormonal preparations, excluding sex hormones and insulins | 1 996,2 | 2,4% | 0,8 | 1,1% |
| J | Antiinfectives for systemic use | 2 208,6 | 2,6% | 0,7 | 1,1% |
| M | Musculo-skeletal system | 1 196,5 | 1,4% | 2,7 | 3,9% |
| V | Various | 964,1 | 1,1% | 0,3 | 0,5% |
| G | Genito-urinary system and sex hormones | 429,5 | 0,5% | 0,9 | 1,3% |
| ~ | Medicaments, without ATC-group | 282,5 | 0,3% | 0,2 | 0,2% |
| S | Sensory organs | 197,2 | 0,2% | 1,5 | 2,1% |
| D | Dermatologicals | 21,0 | 0,0% | 0,2 | 0,2% |
| P | Antiparasitic products, insecticides and repellents | 1,0 | 0,0% | 0,0 | 0,0% |

The leading groups of drugs according to the ATC classification in the segment by the end of 2014 are:

- [L] Antineoplastic and immunomodulating agents;
- [A] Alimentary tract and metabolism;
- [B] Blood and blood forming organs;
- [R] Respiratory system
- [N] Nervous system;

MANUFACTURERS

Currently, in the Russian Federation on the basis of Russian Industry and Trade Ministry have about 1000 drug manufacturers. The TOP-15 is presented in Table 5. In 2014 cumulative their share was 53,5%. The first places in the ranking of manufacturers occupy foreign companies: NOVARTIS, SANOFI and BAYER. On the fourteen line is OTISIPHARM (ex PHARMSTANDART) - the only domestic manufacturer of the top 20 leading players in the Russian pharmaceutical market. In 2013 domestic manufacturer of pharmaceuticals PHARMSTANDART took 3rd place in TOP-20 leading companies in Russian market. At the end the year there was a reorganization of "PHARMSTANDART" in two companies: OTISIFARM and PHARMSTANDART. As a result, OTISIFARM ranked 14th and PHARMSTANDARD ranked 21th.

Table 5. Top 20 leading manufacturers in the Russian pharmaceutical market 2014

| **Rating** | | **Manufacturers** | | **Value volume, mln rub. 2014** | **Growt, %** | **Share of the market, %** |
|---|---|---|---|---|---|---|
| **2013** | **2014** | | | | | |
| 1 | 1 | NOVARTIS | Swiss | 57 154 | 7,0% | 5,9% |
| 2 | 2 | SANOFI | France | 51 751 | 8,3% | 5,4% |
| 4 | 3 | BAYER | Germany | 38 136 | 9,6% | 4,0% |
| 6 | 4 | TAKEDA | Japan | 30 303 | 13,0% | 3,1% |
| 5 | 5 | TEVA | Israel | 28 881 | 2,6% | 3,0% |
| 9 | 6 | JOHNSON&JOHNSON | USA | 27 702 | 16,2% | 2,9% |
| 7 | 7 | F.HOFFMANN-LA ROCHE | Swiss | 27 201 | -0,5% | 2,8% |
| 15 | 8 | SERVIER | France | 27 043 | 9,0% | 2,8% |
| 8 | 9 | ABBOTT | USA | 26 007 | 5,4% | 2,7% |
| 13 | 10 | PFIZER | USA | 24 285 | 44,7% | 2,5% |
| | 11 | BERLIN-CHEMIE | Germany | 21 940 | 3,7% | 2,3% |
| 11 | 12 | MERCK | USA | 20 451 | 15,8% | 2,1% |
| 12 | 13 | GLAXOSMITHKLINE | UK | 19 911 | 7,7% | 2,1% |
| 3 | 14 | OTISIPHARM | Russia | 19 458 | 3,5% | 2,0% |
| 14 | 15 | GEDEON RICHTER | Hungary | 18 299 | 7,2% | 1,9% |

Appendix 2. The volume of Russian pharmaceutical market compared to other countries.

In 2014, the volume of the global pharmaceutical market reached 1.06 trillion US dollars. In comparison with 2013 it grew in monetary terms amounted to about 7%. Traditionally the fastest growing markets are the countries of Latin America and China. At the end of 2014, Russia was on the 7th place among the world's leading pharmaceutical markets, but due to the weakening of the ruble in dollar terms the market capacity was reduced by 8%. If dynamics continues, in 2015 Russia might shift 1-2 places down (DSM Group, 2015). The volume of pharmaceutical market in the world is presented on Figure 1.

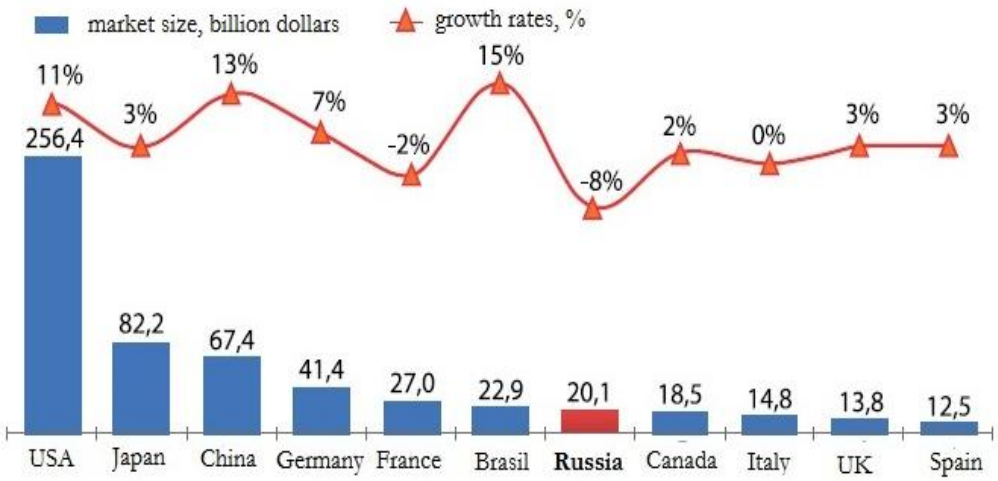



Figure 1. The volume of retail market of Russia and other countries in 2014

The biggest pharmaceutical market is in USA. Only the retail sale of medicines makes up 256.4 billion dollars. European markets (Top 5) together make up 109.5 billion dollars (10% of capacity in the world market) and in 2014 grew by 3%. Russia lags behind average European level of medicines consumption by 3 times and 5 times from the consumption in United States. Less than in Russia ($141) consumption of drugs per person only in Brazil ($122) and China ($ 52) (See Figure 2).

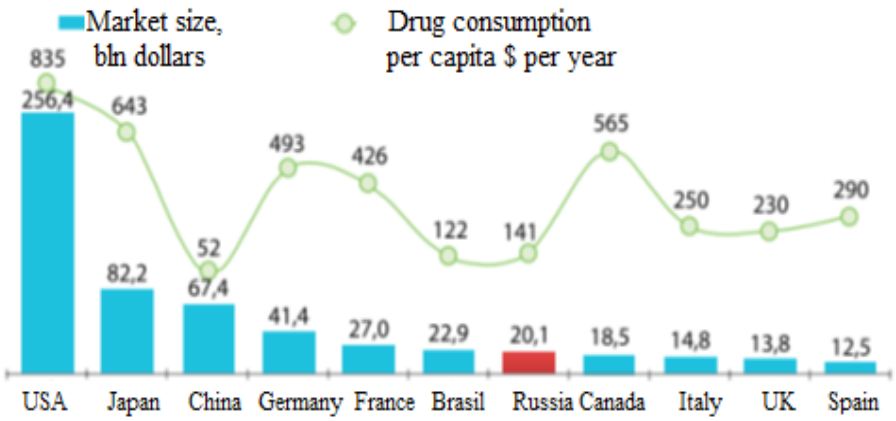



Figure 2. The consumption of medicines in the world, 2014

GMProject®

ISPE Baseline PHARMACEUTICAL ENGINEERING GUIDE

**Certificate of cGMP Compliance No: SZV-AU–5**

***This is to certify that:***

**JSC «Severnaja Zvezda»**

188663 Kuzmolovskij settlement,
Leningrad region,
Russian Federation

Is designed, validate and operate Pharmaceutical facility in **Kuzmolovkskij** for Solid Dosage Form production according:

- **ISPE - Baseline® Pharmaceutical Engineering Guide , Volume 2,** 2nd Edition: Oral Solid Dosage Forms
- **ISPE - Baseline ® Pharmaceutical Engineering Guide, Volume 5,** Commissioning and Qualification, 1st Edition, March 2001

Application of these Engineering Standards is conformable with Directive **2001/83/EC** of the European Parliament and of the Council of November 2001 of the Community code relating to medicinal products for human use - *The Rules Governing Medicinal Products in the European Community, Volume IV, "Guide to Good Manufacturing Practice (GMP) for Medicinal Products".*

Commission Directive **2003/94/E**Cof 8 October 2003, *laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human useThe Rules Governing Medicinal Products in the European Community*

The Compliance with The ISPE Baseline Pharmaceutical Guides and The Guide to GMP for Medicinal Products was audited and reported in written document No.: SZV-AU-5 which is integral part of this certificate

**For and on behalf of G.M.PROJECT and Czech and Slovak ISPE Affiliate:**

*Jiri Moninec*

*Managing director of G.M.PROJECT and Czech and Slovak ISPE Affiliate President*

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**Moscow and Prague, October 23, 2013**

Appendix 4. The license for production.

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ

# ЛИЦЕНЗИЯ

**№ 00003-ЛС** **от 12 февраля 2014 года**

**На осуществление производства лекарственных средств**

Перечень работ, составляющих деятельность по производству лекарственных средств: согласно приложению к лицензии

*Настоящая лицензия предоставлена предприятию (организации)*
**Закрытое акционерное общество "Северная звезда"**
**(ЗАО "Северная звезда")**

*Основной регистрационный номер записи о государственной регистрации юридического лица*
**ОГРН 1027700117983**

*Идентификационный номер налогоплательщика*
**ИНН 7720185196**

Appendix 5. The list of products manufactured by ZAO "Severnaya Zvezda" in 2015.

| № | Name | Pharmacological group |
|---|---|---|
| | Allerfeks, coated tablets 30 mg, 120 mg and 180 mg | Antihistamines |
| | Amiodarone-SZ, tablets 200 mg | Antiarrhythmics |
| | Acyclovir, tablets 200 mg | Antiviral agents |
| | Betahistine, tablets 8 mg, 16 mg and 24 mg | Angioprotektory and proofreaders microcirculation |
| | Bisoprolol, film-coated tablets, 5 mg and 10 mg | Beta-blockers |
| | Verapamil, film-coated tablets, 80 mg | Calcium channel blockers |
| | Verapamil, film-coated tablets, 40 m | Calcium channel blockers |
| | Digoxin, tablets 0.25 mg | Cardiac glycosides and non-glycoside cardiac facilities |
| | Carbamazepine, tablets 200 mg | Antiepileptics |
| | Clopidogrel, film-coated tablets 75 mg | Platelet aggregation inhibitors |
| | Korsavin®, tablet 5 mg | Proofreaders disorders of cerebral circulation |
| | Korsavin® Forte Tablets 10 mg | Proofreaders disorders of cerebral circulation |
| | Lisinopril, tablets 5 mg, 10 mg and 20 mg | ACE inhibitors |
| | loperamide, capsules 2 mg | Antidiarrheals |
| | Meloxicam SZ, tablets 7.5 mg and 15 mg | NSAIDs - Oxicams |
| | Metoclopramide, tablets 10mg | Stimulants gastrointestinal motility (antiemetic) |
| | Methotrexate, film-coated tablets 2.5 mg | Antimetabolites |
| | Olanzapine, film-coated tablets 5 mg and 10 mg | Antipsychotics |
| | Omeprazole, capsules 20 mg | Proton pump inhibitors |
| | Pentoxifylline, tablets, coated with enteric shell, 100 mg | Antiplatelet agents; Adenozinergicheskie tools; Angioprotektory and proofreaders microcirculation |
| | Perindopril, tablets 2 mg, 4 mg | ACE inhibitors |
| | PikogaM®, tablets 50 mg | Nootropics, Proofreaders disorders of cerebral circulation |
| | Pyrazinamide, tablets 500 mg | Synthetic antibacterials |
| | Piracetam, capsules 400 mg | Nootropy |
| | Ramipril-SZ, tablets 2.5 mg, 5 mg and 10 mg | ACE inhibitors, ACE inhibitors in the combinations of calcium channel blockers in combination |
| | Ranitidine, film-coated tablet 150 mg | Antihistamines |
| | Ribavirin-SZ, capsules 200 mg | Antiviral (excluding HIV) agent |
| | Riboxinum, film-coated tablets 200 mg | Anabolic |
| | Simvastatin SZ, film-coated tablets 10 mg, 20 mg and 40 mg | Statins |
| | Tamoxifen tablet 10 mg | Estrogens, progestins; antagonists, and their homologs, antineo-plastic hormones and hormone antagonists |
| | Triduktard®, film-coated with modified release tablets 35 mg | Antihypoxants and antioxidants |
| | Tricho - PIN tablets 250 mg | Synthetic antibacterials |
| | Ursodez® Capsules 250 mg | Hepatoprotectors, Cholagogue and preparations bile, other li-pid-lowering drugs |
| | Furagin tablets 50 mg | Synthetic antibacterials |

Appendix 6. Analysis of the second level product by the ADL matrix.

| № | Question | Industry life cycle stage | | | |
|---|---|---|---|---|---|
| | | **Embryonic** | **Growing** | **Mature** | **Aging** |
| **ASSESSMENT OF MARKET MATURITY** | | | | | |
| 1 | How fast growing market of the product? | rapid growth | moderate growth | not growing, stagnates | falls |
| | | 0 | 1 | 0 | 0 |
| 2 | How high is the market potential? | very high, the market being formed | moderately high | insignificant, almost peaked | no potential, the market peaked |
| | | 0 | 1 | 0 | 0 |
| 3 | What is the consumption of the product among the target audience? | very small, just formed | rapidly increasing every year | almost all the consumers enjoys the product or service | enjoyed by all, or there is a decline of interest in the category |
| | | 0 | 0 | 1 | 0 |
| 4 | How would you assess the level of competition in the market | low: 1-3 players, practically do not compete with each other | growing: the number of competitors is growing, competitive market environment is constantly changing | settled: the number of players practically not growing, competitive market map is formed and virtually unchanged | the number of players do not grow and even decreases |
| | | 0 | 1 | 0 | 0 |
| 5 | The level of investment in the market increases or decreasing? | growing rapidly | moderate growth | constant | decreases |
| | | 0 | 1 | 0 | 0 |
| 6 | How would you assess the level of prices market? | increased, companies receive excess profits | reduced due to new entrants, the threat of price wars | The price level is formed and practically does not change. Each competitor takes a stable price niche | stable or declining |
| | | 0 | 1 | 0 | 0 |
| TOTAL | | | **5** | **1** | |

| № | Question | Competitive position | | | | |
|---|---|---|---|---|---|---|
| | | **Dominant** | **Strong** | **Favorable** | **Tenable** | **Weak** |
| **ASSESSMENT OF COMPETITIVENESS** | | | | | | |
| 1 | How would you assess the dynamics of sales of the product on the market? | The leader in terms of sales. The growth rate of the lowest to the highest, but stable. | The sales volume good and stable (product among the top three market leaders). The rate of growth than or equal to or above the market | The sales volume good and stable, but the product is not the market leader. Perhaps leadership in specific market niches. Growth rates either equal or higher than the market. | The sales volume is low. Constant fluctuations in the level of sales (except for seasonal fluctuations). | The sales volume is low. The downward trend in sales. |
| | | 0 | 0 | 1 | 0 | 0 |
| 2 | How would you assess the competitive advantage of your product? | The product is unique in the industry. | The product has high consumer qualities. it has its own unique properties, which are valued audience. | There is competitive advantage, but it is also necessary to strengthen and bring it to the target audience. | Competitive advantage is easy to copy. In the case of the arrival of a strong player in the industry - the loss of sales. | No competitive advantages. |
| | | 0 | 1 | 0 | 0 | 0 |
| 3 | How would you assess the level of loyalty of your customers and the ability to switch to their competitors' products? | The high proportion of loyal customers. Nobody refuses a product or service. | The high proportion of loyal customers. Minimal risk of switching to competitors, even in the face of declining prices. | Loyalty to a certain extent due to the price level. By reducing the price the market is the threat of withdrawal of consumers to competitors. | Loyalty is missing. Customers can at any time go to competitors. | Loyalty is low and steadily declining. Customers leave. |
| | | 0 | 0 | 1 | 0 | 0 |
| 4 | How would you assess the level of knowledge among the audience of your product? | The most famous product on the market. | The product is in the top ranking of the most famous players in the market. | The average level of knowledge. Not included in the top, but not an outsider. | The low level of knowledge. | Product knowledge is almost absent. |
| | | | | 1 | | |

| № | Question | Competitive position | | | | |
|---|---|---|---|---|---|---|
| | | **Dominant** | **Strong** | **Favorable** | **Tenable** | **Weak** |
| 5 | How would you assess the level of freedom in setting prices for the product?* | Our company dictates the price for the entire market. We do not feel the restrictions of competition in setting prices. | Guided by the average level of prices in the market, but have the ability to set prices above the market average. | The freedom in setting prices only for certain groups of consumers who know and appreciate the company's product. For the rest of the market is difficult to justify higher prices. | Practically there is no freedom in setting prices. Prices are close to average. | Prices are dictated by the market. There is no possibility of price increases. |
| | | 0 | 0 | 0 | 0 | 1 |
| 6 | How would you assess the level of threat from competitors? | The threat is absent. No strong competitors. | The low level of threat. | The average level of threat. High competition for the customer. | The high level of threat. At any time, competitors can take away market share. | Competitors capture our market share. |
| | | 0 | 0 | 1 | 0 | 0 |
| TOTAL | | 0 | 1 | 4 | 0 | 1 |

* Prices of medicines are regulated and controlled by the state.

Appendix 7. Analysis of the second level product by the I. Ansoff matrix.

Step 1: Consider the growth opportunities in the current market with the current item.

| **The strategy of penetration** | **Q: Are there opportunities and growth prospects in the current market for the company?** | | |
|---|---|---|---|
| | **Possible** | **Likely** | **Impossible** |
| Describe the current market and the current product | Current market: Cardio<br>Current commodity: medicinal agent for normalizing blood cholesterol (Statins) | | |
| Market growth rate | High | Slow down, but growing | The stagnation or decrease in volume market. |
| The level of consumption of goods among the target audience | Lower than average | At the level of the average indicators | Higher than average |
| The frequency of product use | Maximum | Moderate | Low |
| The level of goods distribution on the market (or access to the product) | Lower than average | At the level of the average indicators | Higher than average |
| Brand awareness | Lower than average | At the level of the average indicators | Higher than average |
| Economies of scale | Yes | | No |
| Goods of the company has a competitive advantage in the current market (compared to competitors products) | Yes | | No |
| Opportunities to high level of investments | Yes | | No |

Step 2: Considering expanding the current product to new markets.

| **Market development strategy** | **Q: Will the company enter with the current product into new markets?** | | |
|---|---|---|---|
| | **Possible** | **Likely** | **Impossible** |
| Describe the new market and the current product | New market: wholesale and retail trade in new regions of the Russian Federation. Current commodity: medicinal agent for normalizing blood cholesterol (Statins) | | |
| The company is successful in current activity (product of the company is in demand in the current market or high loyalty to it) | Yes | There are minor shortcomings | No, it is necessary to improve the product |
| Number of players in the new market | Small amount of players (1-3) | The average level of market saturation (3-10) | The high level of market saturation |
| Barriers to entry in a new market | Almost absent | Yes, but not high enough | The high level of entry barriers |
| The growth rate of a new market | High | Slow down, but growing | The stagnation or decrease in volume market |
| This product has unique properties, has a competitive advantage (in comparison with the major players in the market), or company owns a unique technology, or the company has a unique profitable business model. | Yes | | No |
| The company has additional capital for investment in the development of new markets. | Yes | | No |

Step 3: Consider the possibility of creating a new product in the current market

| **Product Development Strategy** | **Q: Will the company successfully expand the range of products in the current market?** | | |
|---|---|---|---|
| | **Possible** | **Likely** | **Impossible** |
| Describe the current market and new product | Current market: Cardio<br>New product: extension of product "Statins" due to the new INN (Atorvastatin and Rosuvastatin) | | |
| The growth rate of the current market | High | Slow down, but growing | The stagnation or decrease in volume market. |
| The size of the current market (for the company's business) | Large | Medium | Small |
| Current product is obsolete, has flaws or is in the final stage of the product life cycle | Yes | There is a tendency to reduce the demand for current product | No |
| Intersectoral competition | High | The tendency to tightening | Low |
| The threat of entry of new players | Yes | | No |
| The success of the industry depends on innovation and continuous offer of new products | Yes | | No |
| Update level of assortment and the emergence of new products from key competitors | High | Medium | Low |

Step 4: Consider the possibility of creating a new product in new markets

| **Diversification strategy** | **Q: Is there a need to diversify the company's portfolio?** | | |
|---|---|---|---|
| | **Possible** | **Likely** | **Impossible** |
| Describe the new market and new product | New market: wholesale and retail trade in new regions of the Russia, the new joint program specifications, the product of different pharmacological groups (Ursodez® + "Statins")<br>New product: extension of product "Statins"due to the new INN Atorvastatin and Rosuvastatin | | |
| The growth rate the company's current markets | The stagnation or decrease of market volume | Slow down, but growing | High |
| The competition in the current market | High | The tendency to tightening | Low |
| The company has additional resources for business development in the new market | Yes | | No |
| The company has a certain level of competence (or can achieve it) to do business in a new market | Yes | | No |
| Growth opportunities in the current market, and with the help of current products | Minimal or absent | | Yes |

Step 5: Consider the analysis results in a free form and develop directions of works

| Strategy | Possibility | Description | KEY SOURCES OF GROWTH |
|---|---|---|---|
| Penetration | Likely | The company has the resources to implement the strategy. It is necessary to stimulate progress. Expand the contract with distributors and marketing contract with the pharmacy chains. Maintain the competitiveness of the product. Sell more products to more customers. | • Extend the product "Statins;<br>• Stimulate promotion (to provide training to physicians and pharmacists, participation in exhibitions, etc.);<br>• Using brands and umbrella brands as a promotion;<br>• Programs of combined prescription of medications from different pharmacological groups ( For example Ursodez® + "Statins");<br>• Geographical development and expansion of the wholesale and retail networks; |
| Market development | Impossible | Despite the fact that the company has sufficient resources to implement the strategy, it is not recommended to choose. The volume of production is small compared to the leaders, and there is a risk not to take market share. Sales can only grow at the expense of geographical development (wholesale and retail sales in new regions of Russia). Increase the share of wholesale and retail networks in existing areas. | |
| Product development | Possible | The company has the resources to implement the strategy. The risks are minimal. There are growth opportunities in the current market with the help of current and new products. It is recommended to extend the product "Statins" by the new INN Atorvastatin and Rosuvastatin. It is recommended to brand old products. | |
| Diversification | Likely | The company has the resources to implement the strategy. High risks. There are growth opportunities in the current market with the help of current and new products. It is recommended to extend the product "Statins". | |

Appendix 8. Neuro-SZ products allocation.

| I | NEURO - SZ (therapeutic effect) | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| II level Pharmacological group | Improving brain blood circulation | | | | | | | | | Antipsychotic | | | | | | | | |
| | Improves cerebral blood flow | | Nootropics | Histamine drug | | | | | | Neuroleptics | | | | | | | | |
| III level (INN) INN | Vinpocetine | Vinpocetine | Nicotinoyl gamma-aminobutyric acid | Betahistine | | | | | | Risperidone | | Olanzapine | | Quetiapine | | | | |
| Trade name | Korsavin | Korsavin forte | PicogaM | INN | | | | | | INN | | INN | | INN | | | | |
| Dose, mg | 5 | 10 | 50 | 8 | 16 | | 24 | | | 2 | 4 | 5 | 10 | 25 | 100 | 200 | | |
| Packaging Cell Counter | PCC №50 | PCC №30 | PCC №30 | PCC №30 | PCC №30 | PCC №60 | PCC №20 | PCC №30 | PCC №60 | PCC №20 | PCC №20 | PCC №28 | PCC №28 | PCC №60 | PCC №60 | PCC №60 | | |
| Product development | | | | New dose 32 mg with prolonged action | | | | | | | | | | NEW | | | | |

Appendix 9. Gastro-SZ products allocation.

| | | | | |
|---|---|---|---|---|
| I | | **GASTRO - SZ (therapeutic effect)** | | |
| II level Pharmacological group | | **Improve liver functioning and gallbladder** | | |
| | | **Hepatoprotective agent** | | |
| III level (INN) | INN | **Ursodeoxycholic acid** | | |
| | Trade name | **Ursodez** | | |
| | Dose, mg | **250** | | |
| | Packaging Cell Counter | **PCC №10** | **PCC №50** | **PCC №100** |
| **Product development** | | | **Ursodez forte, capsules 500 mg** | |

Appendix 10. ONCO+ products allocation.

| I | | ONCO + (Acting on a cellular level - therapeutic effect) | | | | | |
|---|---|---|---|---|---|---|---|
| II level Pharmacological group | | Antiviral agents | | Antineoplastic agents | | | |
| | | Treatment of chronic hepatitis | Treatment of herpes and skin infections | Antitumor hormonal and hormone antagonists | | Antimetabolites | |
| III level (INN) | INN | Ribavirin | Acyclovir | Tamoxifen | | Methotrexate | |
| | Trade name | Umbrella brand | Umbrella brand | INN | | INN | |
| | Dose, mg | 200 | 200 | 10 | | 2,5 | |
| | Packaging: 1) Cell Counter 2) Pharmaceutical bottles | PCC №60 | PCC№20 | PB №20 | PCC №30 | PB №50 | PCC №30 |
| Product development | | PCC №120 | Acyclovir forte 400 mg | | | | |

Appendix 11. Potency products allocation.

| I | | Potency (therapeutic effect) | | | | |
|---|---|---|---|---|---|---|
| II level Pharmacological group | | Improving erectile function | | | | |
| | | Potency regulators | | | | |
| III level (INN) | INN | Sildenafil | | | | |
| | Trade name | INN | | | | |
| | Dose, mg | 25 | 50 | | 100 | |
| | Packaging Cell Counter | -- | PCC №1 | PCC №4 | PCC №1 | PCC №4 |
| Product development | | NEW | | | | |

Appendix 12. Allergy products allocation.

| I | Allergy (therapeutic effect) | | | |
|---|---|---|---|---|
| II level Pharmacological group | Antiallergic agent | | | |
| III level (INN) INN | Fexofenadine | | | |
| Trade name | Allerfex | | | |
| Dose, mg | 120 | | 180 | |
| Packaging Cell Counter | PCC №10 | PCC №20 | PCC №10 | PCC №20 |
| | | | | |

Appendix 13. Assessment of economic efficiency of implementation of the product portfolio management model.

Characteristics of the investment project.

The project is in optimizing the product portfolio of the enterprise and in changing the products promotion technology. A more progressive promotion technology is proposed. The project is attributed to the category of projects "for changing" with maintaining of the production capacity. Efficiency calculation is performed on the basis of the accrual approach. The source (background) variant is keeping production and promotion programs unchanged, without implementation of the project. The main variant is a new program for promotion in the course of project implementation. Efficiency is revealed with comparison of indicators with the main and the source (background) variant. The project does not provide changes in production and auxiliary facilities, production capacity and equipment stock.

The number of factory personnel will not be changed during implementation of the project. Development of pharmaceutical compositions, production technologies, and working with experimental production batches will be performed by existing staff by making changes to the production plan. The manufacturing facility works in 2 shifts, the sales office works from 9 a.m. to 6 p.m.

The term of implementation of the project is 4 years, which approximately complies with the statutory term of repayment of products in the pharmaceutical industry. A calculation step is equal to 1 year. Approximate project implementation calendar schedule:

- Year 0: accumulation of funds for the project, market monitoring, enterprise product portfolio analysis, development of the action plan for improvement of the product portfolio (2014).
- Year 1: performance of marketing studies regarding markets of selected directions (products), development of pharmaceutical compositions and manufacturing technologies for the selected products, procurement of missing equipment, and working with experimental and production batches of products, performance of the required studies, registration with the Ministry of Health, launching of new SKUs to the market, taking measures for promotion and attraction of new customers (2015). The

plant use factor for the 1st year is 0.85 (85%). For the 2nd and subsequent years, the plant use factor will be 1.0 (100%) per year.

- Year 2: continuation of the required studies of products, registration with the Ministry of Health of the Russian Federation and the CIS, launching of modified products to the market of the Russian Federation and launching of "old" products to new CIS markets, taking measures for promotion and attraction of new customers (2016).
- Year 3: continuation of registration of new products with the Ministry of Health, launching of new products to the market, taking measures for promotion and attraction of new customers, analysis of the product portfolio, and development of correction measures (2017).
- Year 4: taking measures for promotion and attraction of new customers, marketing research, analysis of the product portfolio, and determination of new products (2018).

The discount rate is calculated with a cumulative method, according to which the discount rate is the sum of the risk-free (basic) rates and surcharges (premium) for risk

$r = r_{бр} + r_p$ ,

where $r_{бр}$ is the risk-free (basic) rate;

$r_p$ is the premium for the risk.

The risk-free interest rate should be refinancing rate of the Central Bank of the Russian Federation, which is 8% p.a. The premium for the risk is assumed as 3%.

$r = 8 + 3 = 11\%$,

The project is attributed to medium risk projects as most of measures proposed by the author provide for output of well-known products under known or new technologies with existing production facilities. The actual discount rate is selected as 11%. It is planned to fund the project with equity funds of the enterprise.

The following are calculations of profit and loss indicators.

Calculation of capital-forming investments is set forth in Table 1.

Table 1. Calculation of capital-forming investments

| **Investment Costs** | **Calculation procedure** | **Amount, thousands rub.** |
|---|---|---|
| New equipment acquired | Cost of new equipment plus installation cost (20%) | 1000 |
| Used equipment available at the enterprise to be applied for the project | Cost of the available equipment at the residual balance cost (the wear is 40%) | 12446 |
| Non-capitalized expenses | Marketing study<br>Development of pharmacological composition<br>Clinical and additional studies<br>State registration<br>Patent expenses<br>Research and development | 30130 |
| Total investment costs | | 44576 |
| Exclusive of the cost of used equipment | | 31130 |
| Initial cost of the new equipment acquired (excl. of VAT) | Cost of new equipment indicated in clause 1 and divided by 1.18. | 800 |
| Initial cost of the used equipment (excl. of VAT) | Residual cost of clause 2 divided by the wear factor | 8890 |

Comparison of the source and the basic variant were revealed factors of changes, economic consequences and changing items of operational costs. (See Table 2)

Table 2. An analysis of the changes and their economic consequences

| **Factor of changes** | **Economic Implications** | **The amended article costs** |
|---|---|---|
| Implementation of the modified drug, SKU optimization | Lower costs for raw materials.<br>Reduced power consumption. | Basic materials<br>Electric energy |
| Retrofitting park equipment, purchase of additional equipment | Due to the increase in the cost of park equipment:<br>Increases the cost of maintenance and repair of equipment<br>Increased amortization of equipment | Maintenance and repair of equipment<br>Amortization |

On the basis of the data in Table 1, calculation of changing operation costs on the source and the basic variant has been performed. It results are summarized in Table 3.

Table 3. Calculation of change (savings or gains) in operating costs for the project implementation

| **Article expenses** | **The original version** | | **The basic version** | | **Saving "+" gain "-"** |
|---|---|---|---|---|---|
| | **Amount, thousand rub..** | **Note** | **Amount, thousand rub..** | **Note** | |
| **1** | **2** | **3** | **4** | **5** | **6** |
| Variable expenses for year | | | | | |
| Basic materials | 452114 | According to the company's' data | 427676 | Decrease consumption rates by 5% | 24469 |
| Energy | 3199 | Same | 2996 | Decrease consumption rates by 7% | 203 |
| Total variable cost savings of making full use of the equipment ( for 2nd and subsequent years) | | | | | 24672 |
| Total variable cost savings in the utilization rate of equipment 0.85 (1st year) Calculation: 24672 * 0.85 | | | | | 20971,2 |
| Fixed costs for the year | | | | | |
| Maintenance and repair | 249 | 2% of the total cost | 259 | 2% of the total cost | -10 |
| Итого прирост постоянных затрат (без амортизации) за год | | | | | 10 |
| Equipment amortization | 1245 | 10% of the total cost of the equipment | 1249 | 10% of the total cost of the equipment | -4 |
| Note. Cost savings is taken into account as part of further inflows. Gain costs are taken into account as part of outflows from operating activities. | | | | | |

**Calculation of Economic Efficiency Indicators**

As the project is funded with equity funds of the enterprise, monetary flows (differences between inflows and outflows) have been determined only for operational and investment activities. Calculation of economic efficiency indicators is performed in Table 4.

The following are explanations of the calculation.

Operational cash inflows (cl.1) comprise of economy of temporary costs taken from Table 3. Operational cash outflows (cl.3) are taken from Table 3 in accordance with continuous costs articles (excl. of depreciation), where growth is observed. Depreciation of new equipment (cl.4) is determined on the basis of the initial cost (excl. of VAT) of the equipment acquired (see cl.4 of Table 3) with the depreciation rate of 10%. This article is for

reference only and is not used in the course of calculation of the resultant cash flows. It is only used for calculation of growth of the income tax.

Growth of the income tax (cl.5) is calculated on the basis of the fact the total decreasing of operational costs is equal to the growth of profits from sales. With the rate of 20% of profits (or, correspondingly, from the total decreasing of operational costs), it is calculated as follows: (cl.2 – cl.3 – cl.4)*0.2. If the profit growth is negative, the income tax growth is equal to zero. The property tax growth (cl.6) is calculated at the rate of 2.2 percent of the average annual cost of the acquired fixed assets (excl. of VAT) with the following formula:

$Н_{имt} = S_{пол} * [1 – Н_{ам} *(t-0.5)]*0,022,$

where 0.022 is the property tax rate;

$S_{пол}$ is the full initial cost (excl. of VAT) of the acquired fixed assets (new equipment), see Table 1, cl.5;

$Н_{ам}$ is the average annual depreciation rate for the acquired equipment, in our example: 0.1 (10%);

t is the ordinal number of year (calculation step).

Total operational outflow (cl.7) is the sum of cl.3, cl.5, and cl.6. Operational cash flow (cl.8) is the difference between inflows and outflows (cl.2 to cl.7). Capital-forming investments (cl.9): see Table 1. Investment activities cash flow (cl.11) is the difference between inflows and outflows (cl.10 to cl.11). Total cash flow (Cl.15) is the sum of cash flows in operational, investment, and financial activities (cl.9 + cl.11 + cl.14). Discount rate (cl.16) is determined by the formula of the fourth function of the monetary unit: $K_{disc}=1/(1+r)^t$, where r is the discount rate (0,11); t is the ordinal number of year. Total cash discount rate (cl.17) is the product: cl.15 * cl.16. Operational activities cash discount flow (cl.19) is the product of cl.8 * cl.16. Investment activities cash discount flow (cl.19) is the product of cl.11 * cl.16. Growth of net present value on the project (cl.21) is the sum under cl.17 or the last number of cl.18.

The discounted transactions profitability index (cl.22) is the ratio of the amount of operational discounted cash flow to the absolute value of the cash flow under investment activities: amount under cl.19 / |amount under cl.20|. Discounted payback period (cl.23) is the moment of time after commencement of the project when accumulated total discounted

cash flow changes its value from negative to positive (see cl.18). It is determined by the following formula:

$$T_{ок} = t + \frac{|ДДП_{нак t}|}{ДДП_{t+1}},$$

where t is the last year in which the accumulated total discounted cash flow under the project was negative (in this example, t = 2);

$|ДДП_{нак_t}|$ is the absolute value of accumulated total discounted cash flow in year t, in our case, | -5,975| thousand rub., see cl.19;

$ДДП_{t+1}$ is discounted cash flow in year t + 1, in our case, 20,182 thousand rub., see cl.18

$T_{ок}$ = 2 + (5,975/20,182) = 2.3 years or 2 years and 3 months.

Table 4. Calculation of economic (commercial efficiency of the project)

| **Indicators by years:** | **0** | **1** | **2** | **3** | **4** |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| The utilization of equipment | | 0,85 | 1 | 1 | 1 |
| OPERATING ACTIVITIES | | | | | |
| Cash inflows | | | | | |
| 1) Variable cost savings | 0 | 20971 | 24672 | 24672 | 24672 |
| 2) Total inflows from operating activities | 0 | 20971 | 24672 | 24672 | 24672 |
| Cash outflows | | | | | |
| 3) The growth of fixed costs | 0 | 10 | 10 | 10 | 10 |
| 4) Reference: depreciation of fixed assets thousand rub. | 0 | 4 | 4 | 4 | 4 |
| 5) The growth of income tax | 0 | 4191,4 | 4931,6 | 4931,6 | 4931,6 |
| 6) The growth of property tax | 0 | 17 | 15 | 13 | 11 |
| 7) Total cash outflows from operating activities | 0 | 9183 | 14875,8 | 9915,2 | 4956,6 |
| 8) Cash flow from operating activities | 0 | 11788 | 9796,2 | 14756,8 | 19715,4 |
| INVESTMENT ACTIVITIES | | | | | |
| Cash inflows | | | | | |
| 9) The market value of released equipment | 0 | 0 | 0 | 0 | 0 |
| Cash outflows | | | | | |
| 10) Capital forming investments (without the cost of used equipment) | 31130 | 0 | 0 | 0 | 0 |
| 11) Cash flow from investing activities | -31130 | 0 | 0 | 0 | 0 |
| FINANCING ACTIVITIES | | | | | |
| Cash inflows | | | | | |
| 12) Total cash inflows from financing activities | 0 | 0 | 0 | 0 | 0 |
| Cash outflows | | | | | |
| 13) Total cash outflows from financing activities | 0 | 0 | 0 | 0 | 0 |
| 14) Cash flow from financing activities | 0 | 0 | 0 | 0 | 0 |

| **Indicators by years:** | **0** | **1** | **2** | **3** | **4** |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| | | | | | |
| 15) Total cash flow for the project | -31130 | 11788 | 9796,2 | 14756,8 | 19715,4 |
| 16) The discounting factor (at a discount rate of 11%) | 1 | 0,9009 | 0,8116 | 0,7312 | 0,6579 |
| 17) The total discounted cash flow for the project | -31130 | 13085 | 12070 | 20182 | 29967 |
| 18) Accumulated result | | -18045 | -5975 | 14207 | 44174 |
| 19) Discounted cash flow from operating activities | 0 | 13085 | 12070 | 20182 | 29967 |
| 20) Discounted cash flow from investing activities | 31130 | 0 | 0 | 0 | 0 |
| INDICATORS OF PROJECT EFFECTIVENESS | | | | | |
| 21) NPV increase in the project | 44174 | | | | |
| 22) Profitability index of discounted investment | 2 | | | | |
| 23) Discounted payback period, years | 2,3 | | | | |
| 24) Internal rate of return (IRR) | 18% | | | | |

Internal rate of return (IRR; see cl.24) is the value of the discount rate with which the NPV of the project turns to zero with other equal conditions. It is determined with the IRR function in MS EXCEL with the input from the line of accumulated cash flow on the project (cl.15).

IRR can be approximately determined by building a graph that shows dependency of the project NPV on the r discount rate. The NPV line = $f(r)$ crosses the zero point only once. To the left, near the zero point, point 1 is found on the line with the following coordinates: $+NPV_1$, $r_1$. To the right, near the zero point, point 2 is found on the line with the following coordinates: $-NPV_2$, $r_2$. The points are connected with a straight line and the point of crossing of the line with the horizontal axis is found, which indicates the IRR value.

Appendix 14. Activities to improve the product portfolio of ZAO «Severnaya Zvezda».

| **Activities** | **Development of a new INN product** | | **Modification of the INN product** | | **NEW SKU** | **Geographic expansion: Medicines for countries of the CIS** | **Transfer of production rights** |
|---|---|---|---|---|---|---|---|
| Research | 1. Market research | 300 000 rub./1 month | 1. Market research | 100 000 rub./ 1 month | Demand is detected during sales | 1. Market research 200 000 rub./ 1 month | No |
| Production | 2.1. Development of pharmaceutical compositions and production technology,<br>2.2. Purchase of missing equipment<br>2.3. Production of trial batch<br>2.4. Establishment of industrial regulations | 1500 thous. rub. /4 months | 2.1. Development of pharmaceutical compositions and production technology,<br>2.2. Purchase of missing equipment<br>2.3. Production of trial batch<br>2.4. Establishment of industrial regulations | 500 thous. rub. / 2 months | 100 thous. rub. / 2 months | 2.1. Production of trial batch<br>2.2. Establishment of industrial regulations<br><br>100 thous. rub. / 2 months | No |
| Clinical studies | Preclinical, clinical and other studies | 4900 thous. rub. / 12 months | Additional studies | 675 thous. rub./ 4 months | No | If required | No |
| Registration in the Ministry of Health | Yes | 300 thous. rub. / 16 months | Yes | 225 thous. rub. / 10 months | Yes | Yes 200-300 thous. rub. / 10 months | Yes 150 thous. rub. |

| Activities | Development of a new INN product | | Modification of the INN product | | NEW SKU | Geographic expansion: Medicines for countries of the CIS | Transfer of production rights |
|---|---|---|---|---|---|---|---|
| Market launch | Yes | 1 000 thous. rub. /3 months | Yes | 500 thous. rub. /3 months | Yes | Yes<br>500 thous. rub. /5 months | Yes |
| Market share | From 0,1 to 3 % | 12 months | Growth up to 5% to the existing share | 4 months | Market share maintained or increased during 1-2 months | Capturing market share during 12 months | No |
| Increasing margins | Due to the development of new market and increase prices | 8 000 thous. rub. /48 months | Due to increase market share, prices and cost reduction | 2000 thous. rub. / 24 months | Due to the market share increase, creation of micro-niches, reducing costs<br><br>(100 thous. rub. / 3 months.) | Due to the market share increase, the establishment of new niches, reducing costs, increasing prices<br><br>(1500 thous. rub. /30 months) | 5 - 7% royalty on sales |